hfma
healthcare financial management association

Physician Fee Schedule Proposed Rule for 2025
Summary Part II: MSSP

Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments [CMS-1807-P]

On July 10, 2024, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule relating to the Medicare physician fee schedule (PFS) for CY 2025[1] and other revisions to Medicare Part B policies. The proposed rule is scheduled to be published in the July 31, 2024 issue of the *Federal Register*. If finalized, policies in the proposed rule generally would take effect on January 1, 2025. **The 60-day comment period ends at close of business on September 9, 2024.**

HFMA is providing a summary in three parts. Part I covers sections I through III.O (except for Section III.G: Medicare Shared Savings Program Requirements) and the Regulatory Impact Analysis. Part II covers the Medicare Shared Savings Program Requirements. Part III covers the updates to the Quality Payment Program.

The policies related to the Medicare Shared Savings Program are designed to strengthen financial incentives for long-term participation and further Medicare's overall value-based care strategy of growth, alignment, and equity, as well as the agency's goal of having 100 percent of individuals under Traditional Medicare in an accountable care relationship by 2030.

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[1] Henceforth in this document, a year is a calendar year (CY) unless otherwise indicated, a reference to "the Act" is a reference to the Social Security Act, and a reference to a regulatory section is a reference to that section in title 42, CFR.

1. Executive Summary

Under the Medicare Shared Savings Program (MSSP), providers and suppliers that participate in an Accountable Care Organization (ACO) continue to receive traditional Medicare fee-for-service (FFS) payments under Parts A and B, and the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements—and in some instances may be required to share in losses if it increases health care spending.[2] CMS reviews in detail the legislative and regulatory history of the Shared Savings Program,[3] with updates regarding the number of participating providers and beneficiaries. As of January 1, 2024, over 10.8 million people with Medicare receive care from one of the over 634,000 health care providers and organizations in the 480 ACOs participating in the MSSP.

CMS states policies in this proposed rule are intended to further advance Medicare's overall value-based care strategy of growth, alignment, and equity, and are to enable timely improvements to program policies and operations. CMS proposes the following policies:

- Changes to the eligibility requirements and application procedures, including:
    - Sunsetting the requirement for CMS to terminate an ACO's participation agreement if the ACO's beneficiary population falls below 5,000 by the end of the performance year specified by CMS in its request for a Corrective Action Plan (CAP).
    - Updating provisions to apply the most recent approach the Department of Justice and Federal Trade Commission use to evaluate ACOs and enforce the antitrust laws.
- Changes to the beneficiary assignment methodology, including (i) revising the definition of primary care services used for beneficiary assignment in order to align the definition with payment policies proposed in the rule that and (ii) broadening the existing exception to the voluntary alignment policy to allow assignment of beneficiaries to entities participating in certain CMMI ACO models even if they had made a voluntary assignment election.
- Changes to the quality reporting requirements and quality performance standard to incrementally align quality measures ACOs are required to report with quality measures under the Adult Universal Foundation measure set, and to further adoption of digital quality measurement by prioritizing the electronic clinical quality measure (eCQM) collection type while providing the Medicare clinical quality measures (CQMs) as a transitional step, including:
    - Requiring ACOs to report the APM Performance Pathway (APP) Plus quality measure set with an incremental implementation period over performance years 2025 through 2028 during which the measure set will grow to 11 measures beginning with performance year 2028. Collection types available to ACOs for reporting the measure set would be limited to eCQMs and Medicare CQMs.

[2] In this section of the summary, all references to ACOs are to ACOs participating in the MSSP.
[3] Section 1899 of the Act contains statutory provisions of the MSSP, with regulations codified at 42 CFR part 425.

    - Making changes to the methodology for calculating the MIPS Quality performance category score for ACOs, including by requiring ACOs to report on *all* measures in the APP Plus quality measure set, as applicable; applying a Complex Organization Adjustment for virtual groups and APM entities (which includes ACOs) reporting eCQMs, and scoring Medicare CQMs using flat benchmarks in an ACO's first two performance period in MIPS.
    - Extending the eCQM reporting incentive for meeting the MSSP quality performance standard to performance year 2025 and subsequent years.
- The establishment of a prepaid shared savings option under which eligible ACOs that are approved to receive prepaid shared savings would receive advances of earned shared savings that they can use to make investments that would help beneficiaries, with at least 50 percent of the prepaid shared savings required to be spent on direct beneficiary services not payable under Traditional Medicare and up to 50 percent allowed to be spent on staffing and infrastructure.
- Refinements to advance investment payment (AIP) policies, including to allow ACOs to voluntarily terminate the payment option while remaining in the MSSP and to codify a policy for recouping AIPs from ACOs whose participation agreements are terminated by CMS.
- Modifications to the MSSP's financial methodology, including (i) modifying the benchmarking methodology to include a health equity benchmark adjustment, (ii) specifying a calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts used in financial calculations upon reopening a payment determination, and (iii) establishing a means to identify significant, anomalous, and highly suspect (SAHS) billing activity and mitigate the impact of such activity on MSSP financial calculations.
- Modifications to the beneficiary information notification requirements, including changing the timing requirement for the follow-up communication (so that it would be required within 180 days from the date of provision of the standardized written beneficiary notice) and narrowing the scope of FFS beneficiaries to whom an ACO under preliminary prospective assignment with retrospective reconciliation would be required to provide the standardized written notification.

CMS also issues a request for information seeking comments on financial arrangements that could allow for higher risk and potential reward under a revised ENHANCED track.

As a result of the MSSP policies in this proposed rule, CMS projects a $260 million decrease in total program spending over the 10-year period 2025 through 2034. These changes are anticipated to support growth in this program with a particular focus on including underserved beneficiaries.

2. Eligibility Requirements and Application Procedures

a. Overview

CMS proposes two modifications to the Medicare Shared Savings Program (MSSP) eligibility and application procedures, which are discussed in further detail under sections (b) and (c) and would be implemented for performance years beginning on or after January 1, 2025:

- Sunset the requirement that CMS must terminate the participation of an ACO (and the related restriction that the ACO is no longer eligible to share in savings for the performance year) if the ACO's assigned population is below 5,000 at the end of the performance year specified by CMS in its request for a Corrective Action Plan (CAP).
- Revise the antitrust language in the application procedures for the MSSP.

b. Monitoring Compliance with the Requirement that ACOs Maintain at least 5,000 Assigned Beneficiaries

ACOs participating in the MSSP are required by statute to include primary care ACO professionals that are sufficient for the number of Medicare FFS beneficiaries assigned to the ACO and to have at least 5,000 such beneficiaries assigned to it.[4] An ACO's assigned population may vary during the agreement period. If an ACO's assigned population falls below 5,000 beneficiaries at any time during the performance year, CMS generally issues a warning notice and requests the ACO submit a CAP. If the ACO's assigned population is below 5,000 at the end of the performance year specific in the CAP, CMS is required under its regulations to terminate the ACO's participation, and the ACO is no longer eligible to share in savings for the performance year.

Separately, for purposes of calculating an ACO's shared savings and shared losses, CMS has established a policy that provides for ACOs in two-sided risk models to select from one of three options for their Minimum Savings Rate (MSR)/Minimum Loss Rate (MLR), including fixed and variable MSR/MLRs. ACOs in one-sided risk models use a variable MSR/MLR that varies based on the number of beneficiaries assigned to the ACO. The MSR/MLR are each thresholds the ACO must meet or exceed to share in savings or be liable for shared losses, respectively. They are each calculated as a percentage of the ACO's updated historical benchmark and are intended to prevent changes in expenditures that represent normal or random variation (and are not representative of an actual change in performance) from resulting in an ACO earning shared savings or being liable for shared losses. When an ACO's assigned beneficiary population decreases, the variability in the populations' expenditures increases, which raised concerns that the reduction in the size of an assigned beneficiary population could result in normal expenditure fluctuations affecting shared savings payments. Therefore, in the December 2018 PFS rule CMS finalized a policy to use a variable MSR/MLR (i.e., an MSR and MLR sliding scale that varies based on the number of beneficiaries assigned to the ACO) when calculating shared savings and shared losses if an ACO's assigned beneficiary population falls below 5,000 for the performance year – regardless of whether the ACO had chosen a fixed or variable MSR/MLR.[5]

[4] See section 1899(b)(2)(D) of the Act. Regulations implementing these requirements are under §425.110.
[5] This policy was finalized in the December 2018 PFS final rule (83 FR 67925 through 67929).

CMS believes the variable MSR/MLR effectively serves to reduce financial risk of allowing ACOs to participate in MSSP if the ACO's assigned beneficiaries decrease in number, and therefore believes the regulatory requirement for CMS to terminate an ACO's participation and eligibility to share in savings is no longer necessary in the case that its assigned population drops below 5,000. The agency proposes to sunset the provision at §425.110(b)(2) so that for performance years beginning on or after January 1, 2025, CMS would no longer be required to terminate the participation agreement of an ACO or end its eligibility for shared savings if its assigned population falls below 5,000.

CMS clarifies the proposal would not affect:

- The requirement at §425.110(a) that implements the statutory requirement that ACOs have 5,000 beneficiaries at critical points in CMS' determination of its eligibility to participate in the MSSP, specifically including at the time of application to be eligible for the program and at any point when an ACO elects to renew its participation in the program.
- The agency's enforcement *authority* pursuant to §425.110(b) to apply enforcement actions under §§425.216 and 425.218, including imposing a CAP on an ACO or terminating its participation agreement, if the ACO's assigned population falls below 5,000 at any time during the performance year.

c. Update Antitrust Language

ACOs that seek to participate in (or enter a new agreement under) the MSSP and were "newly formed after March 23, 2010), as defined in the Antitrust Policy Statement,"[6] are required to allow CMS to share a copy of their application with the Federal Trade Commission (FTC) and the Department of Justice (DOJ).[7] The Antitrust Statement Policy was issued by the FTC and DOJ and was intended to provide guidance to market participants regarding antitrust criteria. In 2023, the FTC and DOJ withdrew the Antitrust Policy Statement on the basis that the policy no longer served its intended purpose and instead stated their intent to enforce antitrust laws in the health care markets by evaluating, on a case-by-case basis, mergers and conduct contrary to competition.

Therefore, CMS proposes, effective January 1, 2025, to remove the reference to the Antitrust Policy Statement from the MSSP eligibility requirements, specifically the references in §§425.202(a)(3) and 425.224(a)(3). The provisions would still require that an ACO that seeks to participate in or enter a new participation agreement under the MSSP would need to agree to share a copy of the application with the FTC and DOJ.

[6] The regulatory provisions cited refer to the Antitrust Policy Statement. The preamble of the rule references the longer title "Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the MSSP."
[7] See §425.202(a)(3) and 425.224(a)(3).

3. Beneficiary Assignment Methodology

a. Proposed Revisions to the Definition of Primary Care Services

Background. Section 1899(c)(1) of the Act specifies that beneficiaries are assigned to ACOs based on their utilization of primary care services provided by a physician who is an ACO professional and all services furnished by rural health clinics (RHCs) and federally qualified health centers (FQHCs). However, a list of services considered primary care services for purposes of beneficiary assignment is not specified in statute.[8]

Proposed Revisions. In order to remain consistent with billing and coding under the PFS, CMS is proposing to include additional codes in the definition of primary care services used in the MSSP assignment methodology for performance years beginning on or after January 1, 2025. Specifically, the agency would specify the revised definition at §425.400(c)(1)(ix) to include the list of HCPCS and CPT codes specified in §425.400(c)(1)(viii) and the following additions:[9]

- *Safety Planning Interventions (HCPCS code GSPI1) when the base code is also a primary care service code*: Section II.I of the rule includes a proposal to create an add-on G-code under the PFS that would be billed along with an E/M visit or psychotherapy visit when the billing practitioner performs safety planning interventions (i.e., development of a personalized list of coping strategies and sources of support when an individual experiences thoughts to harm themselves or others). CMS believes the code, if finalized, is also an appropriate addition to the definition of primary care services, when billed with an E/M visit, since the code is being proposed as an add-on service to an E/M (or psychotherapy visit) and E/M visits are included in such definition for purposes of assignment. Since psychotherapy services are not considered primary care services for purposes of beneficiary assignment, the proposed code when billed with psychotherapy services would not be considered a primary care service for beneficiary assignment – the add-on code would only be included as a primary care service for beneficiary assignment when billed with a service which *is* included in the definition of primary care services for such purpose.
- *Post-Discharge Telephonic Follow-up Contacts Intervention (FCI) (HCPCS code GFCI1)*: Under section II.I of the rule, CMS is proposing a monthly billing code for FCI, as a bundle of services. FCI is a protocol of services for individuals with suicide risk involving a series of phone contacts between a provider and person during a period (which could be weeks or months) following discharge for specified settings. CMS believes including this code, if it is finalized for the PFS payment policy, in the MSSP definition of primary care services for beneficiary assignment would ensure better continuity of care since FCI services are designed to assist in transitions from the ED into the community and because the services under the code reflect the types of services primary care providers are expected to provide to improve care management. The agency

[8] Primary care services are defined for purposes of assigning beneficiaries to ACOs in §425.402 as the set of services identified by the listed HCPCS/CPT codes.

[9] Many of the following additions (that is, all other than Interprofessional Consultation) are new codes being proposed in this rule for inclusion under the PFS, and CMS proposes those new codes be included under the MSSP definition of primary care services for purposes of beneficiary assignment *if* the respective code is finalized for inclusion under the PFS payment policy proposal.

points to similarities between FCI and other services already included in the primary care services definition.

- *Virtual Check-in Service (CPT code 9X091)*: Under section II.E of the rule, CMS proposes separate payment under the PFS for this code. The code description for CPT code 9X091 is the same as (and, per CPT Editorial Panel materials, intended to replace) HCPCS code G2012, which is already included in the MSSP definition of primary care services for beneficiary assignment. CMS is proposing to delete G2012 for purposes of Medicare PFS payment, but will continue to included it in the MSSP definition consistent with how deleted CPT and HCPCs codes have historically been handled (and to allow for consistency for calculating historical benchmarks).[10] If 9X091 is finalized for the PFS payment policy, CMS proposes to include the code under the MSSP primary care services definition.
- *Advanced Primary Care Management (APCM) Services (HCPCS GPCM1, GPCM2, and GPCM3)*: Under section II.G of the rule, CMS proposes to establish three HCPCS codes and make payment under the PFS for APCM services, furnished per calendar month following an initial qualifying visit. The coding and payment is to recognize the resources involved in furnishing services that use an advanced primary care delivery model that is supported by a team-based structure. As proposed under section II.G the coding and payment policies would be for practitioners who are providing services under the specific model of advanced primary care when the practitioner is the continuing focal point for all needed health services and responsible for all primary care services. CMS describes that the proposed codes are designed to bundle individual utilization codes that are already included in the MSSP definition of primary care services for beneficiary assignment[11] and anticipates the codes would mostly be used by primary care specialties or specialists functioning as primary care practitioners. Therefore, the agency believes, if the APCM codes are finalized for the PFS payment policy, it is also appropriate to include these proposed codes in the MSSP definition of primary care services for beneficiary assignment.
- *Cardiovascular Risk Assessment and Risk Management Services (HCPCS codes GCDRA and GCDRM)*: In section II.G of the rule CMS proposes a new stand-alone HCPCS code to identify and value the work involved in administering Atherosclerotic Cardiovascular Disease (ASCVD) risk assessment when medically reasonable and necessary in relation to an E/M visit. Under that section, the agency also proposes that Atherosclerotic Cardiovascular Disease (ASCVD) risk management services (the development, implementation, and monitoring of individualized care plans for reducing cardiovascular risk and counseling and monitoring to improve diet and exercise) be considered a "designated care management service" and, as such, could be provided by auxiliary personnel under the general supervision of the billing practitioner. CMS describes how the proposed codes are similar to codes already included in the MSSP primary care

[10] CMS finalized in the 2022 PFS final rule (86 FR 65277-65279) a policy to incorporate into the primary care services MSSP definition a permanent CPT code when it directly replaces another CPT code or temporary HCPCS code that is already included in the definition for purposes of beneficiary assignment.

[11] Specifically: CCM (CPT codes 99437, 99487, 99489, 99490, 99491, and 99439 and HCPCS codes G0506 and G2058), PCM (CPT codes 99424, 99425, 99426, and 99427 and HCPCS codes G2064 and G2065), TCM (CPT codes 99495 and 99496), remote evaluation of patient videos/images (HCPCS code G2010), and virtual check-in and e-visits (HCPCS codes G2012 and G2252). The proposed codes would also bundle IPC services, which CMS is proposing to include in the MSSP primary care purposes under this section.

services definition and are care and risk management services that include elements of continuous and coordinated care, which the MSSP is to promote, and therefore proposes, that if finalized for the PFS payment policy, the codes also be included under the MSSP primary care services definition.

- *Direct Care Caregiver Training Services (HCPCS codes GCTD1, GCTD2 and GCTD3*): In section II.E of the rule, CMS is proposing new coding and payment for caregiver training services (CTS) for direct care services and supports, which (unlike other caregiver training codes paid under the PFS) focus on specific clinical skills aimed at the caregiver effectuating hands-on treatment, reducing complications, and monitoring the patient. CMS believes that since CTS may be integral to the patient's overall treatment, if the codes are finalized for the PFS payment policy, the services should be included in the MSSP definition of primary care services for beneficiary assignment.
- *Individual Behavior Management/Modification Caregiver Training Services (HCPCS codes GCTB1 and GCTB2)*: Under section II.E of the rule, CMS proposes to establish new coding and payment for caregiver behavior management and modification training. CMS believes that CTS may be reasonable and necessary when integrated to a patient's overall treatment especially when assistance by caregivers receiving the training is necessary to ensure successful treatment outcomes and that therefore, if it is finalized for the PFS payment policy, CTS should be included in the MSSP definition of primary care services for purposes of beneficiary assignment.
- *Interprofessional Consultation (IPC) (CPT codes 99446, 99447, 99448, 99449, 99451, 99452)*: These six codes were finalized in the 2019 PFS final rule (83 FR 59489). They describe assessment and management services conducted through phone, internet, or electronic health record consultations furnished when the treating physician or professional requests treatment advice from a consulting physician or professional with specific expertise without the need for in-person contact. CMS notes that these codes reflect medical practice trends in primary care and patient-centered care and believe they should be included in the MSSP definition or primary care services for beneficiary assignment.

Also, as part of the revised primary care services definition for beneficiary assignment, CMS proposes to specify that the primary care service codes would include a CPT code identified by CMS that directly replaces a CPT code specified in §425.400(c)(1)(ix)(A) or a HCPCS code specified in §425.400(c)(1)(ix)(B), when the assignment window or expanded assignment window (as defined in §425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under Medicare FFS.

CMS seeks comment on the proposals under this section and on any other existing codes or new codes being proposed in this rule that the agency should consider adding to the primary care services definition in future rulemaking.

b. Proposed Revisions to Criteria for ACO Models to Waive MSSP Requirements Giving Precedence for Assignment based on Beneficiary Voluntary Alignment

Background. Medicare FFS beneficiaries may voluntarily identify an ACO professional as their primary care provider for purpose of assignment to an ACO.[12] CMS reviews a limited exception to its voluntary alignment process under §425.402(e), which it has applied to certain CMMI models so as to not require that beneficiaries who previously designated an ACO professional as their primary clinician under those models remain assigned to the ACO. Currently, under the limited exception, CMS would not assign a beneficiary who has voluntarily identified an ACO professional to the ACO when the beneficiary is also eligible for claims-based assignment to an entity participating in a CMMI model if (i) under the model claims-based assignment is based solely on claims for services *other than* primary care services and (ii) the Secretary has determined a waiver under the model (in accordance with section 1115A(d)(1) of the Act) of the voluntary identification of an ACO professional requirement is necessary solely to test the model.

Proposed Revisions. Since CMS finalized the limited exception to the voluntary alignment policy, CMMI models have been developed that use claims for *both* primary care services and services other than primary care for determining claims-based assignment to entities participating in the models. Therefore, CMS proposes to broaden the current exception in the case of disease or condition-specific CMMI models so that a voluntarily aligned MSSP beneficiary would be assigned to an entity participating in a model based on claims if the model bases assignment solely on (1) [proposed additional criterion:] claims for primary care and/or other services related to treatment of one or more specific diseases or conditions targeted by the model or (2) [the current criterion of the exception:] claims for services other than primary care services when the Secretary determines a waiver is necessary solely for purposes of testing the model. That is, beginning for performance year 2025, if a beneficiary voluntarily aligns to an MSSP ACO and is also eligible for claims-based assignment to an entity participating in a CMMI model that uses claims-based assignment that satisfies criterion 1 or 2 described above, then CMS would assign the beneficiary according to the CMMI model assignment and not to the voluntarily aligned MSSP ACO. CMS clarifies that under this exception, the beneficiary may still voluntarily identify an ACO professional participating in an MSSP ACO as their primary clinician and seek care from any clinician, but the beneficiary would not be assigned to that MSSP ACO even if the designated primary clinician is an ACO professional in that ACO.

CMS describes that less than 1 percent of beneficiaries voluntarily aligned to an MSSP ACO would instead be claims-based assigned to an entity in a CMMI model under the exception proposed.

[12] See section 1899(c)(2)(B) of the Act.

4. Quality Performance Standard and Other Reporting Requirements

a. Background

The MSSP's quality performance standard is used to determine whether an ACO is eligible to receive shared savings for a performance year (PY). Determination of whether the standard has been met takes into account the number and type of measures for which an ACO reports data and its measure scores. Beginning with PY 2025, ACOs must report (i) the three electronic clinical quality measures (eCQMs) or clinical quality measures (CQMs) of the APM Performance Pathway (APP) of the Merit-based Incentive Payment System (MIPS) (MIPS CQMs) and (ii) the CAHPS for MIPS survey through the APP. Also, in the 2024 PFS final rule, CMS established the Medicare Clinical Quality Measures for ACOs Participating in the MSSP (Medicare CQMs), which are MIPS CQMs but are reported on an ACO's eligible Medicare FFS beneficiaries (rather than all payer/all patients), as another optional collection type beginning for performance year 2024. Medicare CQMs are intended to serve as a transition collection type to help some ACOs build the infrastructure and expertise to report all payer/all patient eCQMs/MIPS CQMs.

b. Proposal to Require Shared Savings Program ACOs to Report the Alternative Payment Model (APM) Performance Pathway (APP) Plus Quality Measure Set

Overview. CMS reviews the continued concerns expressed by interested parties regarding ACOs' ability to report all-payer/all-patient eCQMs/MIPS CQMs, including concerns about the costs of implementing an infrastructure to enable aggregation of data from multiple ACO participant TINs across varying electronic health record (EHR) systems. Based on continued feedback, CMS believes that further time and support is needed for the widespread adoption of the all-payer/all-patient collection types. In addition, the agency describes its goals to align the APP quality measure set with the Universal Foundation measures and balance this alignment with efforts to reduce burden.

Proposed Revisions.

Proposal to Require MSSP ACOs to Report the APP Plus Quality Measure Set. In section IV.A.4.c(2) of the rule, CMS proposes to create the APP Plus quality measure set to align with the Adult Universal Foundation measures. This measure set would be an optional set for APP reporters. Five out of the ten Adult Universal Foundation measures are already in the APP quality measure set for performance year 2025.[13] There are a total of six measures in the APP quality measure set and under the APP Plus proposal, CMS would incrementally increase the number of measures in the APP quality measure set from performance years 2025 through 2028 to 11 measures – which would be the existing APP quality measure set plus five newly proposed measures from the Adult Universal Foundation measure set.[14]

[13] In addition to the 5 Adult Universal Foundation measures, the Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions is also in the APP quality measure set.
[14] In the 2021 PFS final rule (85 FR 84723), CMS adopted the APP quality measure set, which reduced the total number of measures on which ACOs must report from 23 to either 6 or 13 measures, depending on the reporting option chosen by the ACO.

Beginning for performance year 2025, CMS proposes to require MSSP ACOs to report the APP Plus quality measure set (which is being proposed in section III.G.4.b(2)(a) of the rule) and concurrently sunset MSSP ACOs' reporting of the APP quality measure set. This is consistent with the agency's goal of aligning quality measures across CMS programs, including aligning the quality measures reported by MSSP ACOs with the Value in Primary Care MIPS Value Pathway (MVP) that contains the same Universal Foundation measures. Tables 34, 35, and 36 in the rule show the proposed phase-in of the APP Plus quality measure set for MSSP ACOs. Under the proposal, there would be:

- For performance year 2025: Eight measures (five eCQMs/Medicare CQMs, two administrative claims measures, and the CAHPS for MIPS survey measure).
- For performance years 2026 and 2027: Nine measures (six eCQMs/Medicare CQMs, two administrative claims measures, and the CAPS for MIPS survey measure).
- For performance year 2028 and subsequent performance years: Eleven measures (eight eCQMs/Medicare CQMs, two administrative claims measures, and the CAHPS for MIPS Survey measure).

Proposed Collection Types Available for Shared Savings Program ACOs Reporting the APP Plus Quality Measure Set. CMS proposes that beginning performance year 2025, the eCQM and Medicare CQM collections types would be the only collection types available for MSSP ACOs reporting the APP Plus quality measure set. This would prioritize the eCQM collection type and allow for use of the Medicare CQMs as a transitional approach to digital quality measurement. CMS is not proposing to include the MIPS CQM collection type for reporting the measure set and believes this approach (including the use if the transitional Medicare CQMs) will support ACOs that have invested in eCQMs and still align with the agency's long-term goals of fully transitioning to digital quality measurement for its quality reporting and value-based purchasing programs.

CMS describes its work to convert current eCQMs to the Fast Healthcare Interoperability Resources (FHIR) standard. CMS reviews that the Medicare CQMs are temporary and the agency anticipates that increased use of FHIR Application Programming Interface (API) technology, including among MSSP ACOs, may accelerate the agency's future plans to sunset Medicare CQMs.

In addition, CMS clarifies that FQHCs and RHCs that participate in APMs (such as MSSP) are considered APM entity groups and therefore FQHCs and RHCs that participate in MSSP ACOs would have to report the APP Plus quality measure set through their ACO beginning for performance year 2025.

Proposed Changes to Regulation Text. CMS proposes detailed changes to regulation text at 42 CFR part 425 to implement its APP Plus Quality Measure set proposals described above for MSSP ACOs, and conforming changes. Examples of those regulatory changes include:

- §425.508(b) - Sunset after 2024 the requirement that ACOs must submit quality data via the APP to satisfactorily report on behalf of eligible clinicians billing under the ACO TIN for the MIPS quality performance category of the QPP.
- New paragraph (c) under §425.508 that would require, beginning January 1, 2025, ACOs to submit quality data via the APP on quality measures contained in the APP Plus quality

measure set to satisfactorily report on behalf of eligible clinicians billing under the ACO TIN for the MIPS quality performance category of the QPP.

c. Proposed Changes to the Methodology for Calculating the MIPS Quality Performance Category Score for MSSP ACOs Reporting the APP Plus Quality Measure Set

Background. MIPS eligible clinicians identified on the participation list or affiliated practitioner list of an APM entity participating in a MIPS APM (including ACOs participating in the MSSP) that report data through the APP are scored according to the APP scoring methodology, which is under §414.1367.

- The MIPS cost performance category weight is zero for MIPS eligible clinicians that report through the APP.[15]
- For the Improvement Activities (IA) performance category, a MIPS eligible clinician in an APM for a performance period automatically earns a minimum score of ½ of the highest potential score for the category.
- The Promoting Interoperability (PI) performance category under the APP is reported and calculated as described in §414.1375.
- The ACO's MIPS quality performance score is calculated according to the MIPS scoring rules for the performance category at §414.1380(b)(1), with exceptions. Each submitted quality measure that does not have a benchmark or does not meet the case minimum required is excluded from an ACO's total measure achievement points and total available measure achievement points. Measures that are topped out are not subject to the scoring cap. Each required measure that is not submitted by an ACO receives zero measure achievement points.
- The performance category weights used to calculate the final score for a MIPS eligible clinician scored through the APP are: (i) Quality: 50 percent; (ii) Cost: 0 percent; (iii) IAs: 20 percent; and (iv) PI: 30 percent.[16]

Proposed Revisions.

Proposal to Establish Data Submission Criteria for the APP Plus Quality Measure Set. As described in the preceding proposal, beginning for performance year 2025, ACOs would be scored on all required measures in the APP Plus quality measure set. CMS proposes to apply the policies related to MIPS performance category scoring in the APP at §414.1367(c) to MSSP ACOs that report the APP Plus quality measure set for meeting the MSSP's quality performance standard. Specifically, the following would be applied to MSSP ACOs reporting the APP Plus quality measure set beginning with performance year 2025:

- The APP scoring policies at §414.1367(c)(1) for the calculation of the ACO's MIPS Quality performance category.
- §414.1367(c)(2) for the calculation of an ACO's MIPS Cost performance category.

[15] See the waiver authority for CMMI APMs under section 1115A(d)(1) of the Act and under section 1899(f) of the Act for MSSP.

[16] See §414.1367(d)(1) for the category weights. Under section 1848(q)(5)(F) of the Act, CMS may also reweight one or more of the categories. §414.1367(d)(2) describes CMS' reweighting policies: If CMS reweights the quality performance category to 0 percent, the PI is reweighted to 75 percent and IA to 25 percent; if PI is reweighted to 0 percent, then quality is reweighted to 75 percent and IA is reweighted to 25 percent.

- §414.1367(c)(3) for the calculation of an ACO's MIPS IA performance category.
- §414.1367(c)(4) for the calculation of an ACO's MIPS PI performance category.
- The performance category weights at §414.1367(d) and the calculation of the final score under §414.1367(e).

Proposal to Establish Complex Organization Adjustment for Virtual Groups and APM Entities. Under section IV.A.4.f(1)(b)(iii) of the rule, CMS proposes to establish a Complex Organization Adjustment beginning for the 2025 performance period/2027 MIPS payment year. That proposal would be applicable to MSSP ACOs reporting the APP Plus quality measure set beginning in performance year 2025 because MSSP ACOs are APM entities. Under that proposal:

- A virtual group and an APM entity would receive one measure achievement point for each submitted eCQM that meets the case minimum requirement and data completeness requirement.[17]
- A reported eCQM may not score more than 10 measure achievement points; the total achievement points may not exceed the total available measure achievement points for the quality category.
- The adjustment for a virtual group or APM entity may not exceed 10 percent of the total available measure achievement points in the quality category.
- The adjustment would be added for each measure submitted at the individual measure level.

Proposal to Score Shared Savings Program ACOs Reporting Medicare CQMs using Flat Benchmarks. The performance rate (or threshold) that an ACO must achieve to earn the corresponding quality points for a measure is referred to as the quality performance benchmark for the measure. CMS describes how under the current benchmarking policy, ACOs choosing to report on Medicare CQMs are benchmarked only against other ACOs that are also reporting Medicare CQMs, and not against other MIPS clinicians (as is the case for those reporting eCQMs or MIPS CQMs). This is because Medicare CQMs is a collection type for only MSSP ACOs and only ACO data will be available to benchmark the CQMs. As a result, high-performing ACOs reporting on Medicare CQMs could earn lower measure achievement points relative to other MIPS groups since the Medicare CQM benchmarking pool (i.e., only MSSP ACOs) is made up of higher-than-average performance data (as compared to the larger, more diverse MIPS clinicians pool).

As described above, CMS is proposing in section III.G.4.b(2)(b) of the rule to limit the collection types for MSSP ACOs reporting the APP Plus quality measure set to the eCQM and Medicare CQM collection types. Consequently, CMS proposes in section IV.A.4.f(1)(c)(i) of the rule that beginning with the 2025 performance period/2027 MIPS payment year, Medicare CQM measures would be scored using flat benchmarks (instead of performance period benchmarks) for their first two performance periods in MIPS. Flat benchmarks assign a performance rate range based on decile, and the number of measure achievement points earned for each measure is determined based on the applicable decile and percentile distribution. For non-inverse measures, better performance is indicated by a higher performance rate, thus with a flat benchmark 90

[17] The case minimum requirement can be found at §414.1380(b)(1)(iii) and the data completeness requirement at §414.1340.

percent or above would be the top decile. For inverse measures, better performance is indicated by a lower performance rate, thus with a flat benchmark 10 percent or below would be the top decile. Table 31 of the rule shows the proposed flat benchmarks for non-inverse Medicare CQMs and Table 32 shows flat benchmarks for inverse Medicare CQMs. CMS gives an example of a scenario in which ACOs have a tight distribution of performance rates on a measure as an instance where ACOs would earn higher achievement points under flat benchmarks. Specifically, under the example, CMS points to a non-inverse measure for which a performance rate of 90 percent is in the 8th decile (i.e., a hypothetical performance period benchmark resulting in the ACO reporting the 90 percent performance rate being scored in the 8th decile). But using the flat benchmarks shown in Table 31, the same ACO reporting the 90 percent rate would be scored in the 10th decile, showing that greater measure achievement points in that scenario would be earned with the flat threshold.

d. Proposal to Extend the eCQM Reporting Incentive for Meeting the MSSP Quality Performance Standard

Background. For performance year 2024, an ACO has an additional pathway (the eCQM reporting incentive) to meeting the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses, as applicable. The eCQM reporting incentive is currently set to end after performance year 2024. Under the eCQM reporting incentive, an ACO meets the quality performance standard if the ACO:

- Reports the three eCQMs/MIPS CQMs and meets the data completeness requirements and case minimum requirement for all three;
- Achieves a quality performance score equal to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set; and
- Achieves a quality performance score equal to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set.

Proposed Revisions. CMS proposes to extend the eCQM reporting incentive to performance year 2025 and subsequent performance years. The reporting incentive would not apply to ACOs that report a combination of eCQMs/Medicare CQMs or report only Medicare CQMs. An ACO would meet the quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, as applicable, if the ACO:

- Reports all of the eCQMs in the APP Plus quality measure set applicable to the performance year (under the phase-in) and meets the data completeness requirement for all three;
- Achieves a quality performance score equal to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP Plus quality measure set; and
- Achieves a quality performance score equal to or higher than the 40th percentile of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set.

e. Summary of Proposals

Table 33 of the rule (represented with organizational changes below) summarizes the proposed changes to the APP quality reporting requirements and quality performance beginning for performance year 2025.

Proposed APP Plus Quality Measure Set Reporting Requirements and Quality Performance Standard for PY 2025 and Subsequent PYs (Based on Table 33 in the rule with formatting modifications)			
	PY 2025	**PYs 2026 and 2027**	**PY 2028 and Subsequent PYs**
Quality Reporting Requirements	Report 5 eCQMs/ Medicare CQM in the APP Plus quality measure set; and administer CAHPS for MIPS survey. CMS calculates 2 claims-based measures.	Report 6 eCQMs/ Medicare CQM in the APP Plus quality measure set; and administer CAHPS for MIPS survey. CMS calculates 2 claims-based measures.	Report 8 eCQMs/ Medicare CQM in the APP Plus quality measure set; and administer CAHPS for MIPS survey. CMS calculates 2 claims-based measures.
Quality Performance Standard Including the Proposed Health Equity Adjustment	A health-equity adjusted score that is ≥ the 40th percentile across all MIPS Quality performance category scores (excludes those eligible for facility-based scoring*) OR Report the 5 eCQMs in the APP Plus quality measure set (for each, meet completeness requirement); achieve quality performance score that is ≥ 10th percentile of performance benchmark on ≥ 1 (of 4) APP Plus quality measure set outcome measures and a score equivalent to or > than the 40th percentile of performance benchmark on ≥ 1 of 7 remaining APP Plus quality measure set measures	A health-equity adjusted score that is ≥ the 40th percentile across all MIPS Quality performance category scores (excludes those eligible for facility-based scoring*) OR Report the 6 eCQMs in the APP Plus quality measure set (for each, meet completeness requirement); achieve quality performance score that is ≥ 10th percentile of performance benchmark on ≥ 1 (of 4) APP Plus quality measure set outcome measures and a score equivalent to or > than the 40th percentile of performance benchmark on ≥ 1 of 8 remaining APP Plus quality measure set measures	A health-equity adjusted score that is ≥ the 40th percentile across all MIPS Quality performance category scores (excludes those eligible for facility-based scoring*) OR Report the 8 eCQMs in the APP Plus quality measure set (for each, meet completeness requirement); achieve quality performance score that is ≥ 10th percentile of performance benchmark on ≥ 1 (of 4) APP Plus quality measure set outcome measures and a score equivalent to or > than the 40th percentile of performance benchmark on ≥ 1 of 10 remaining APP Plus quality measure set measures
Alternative Quality Performance Standard	Fails to meet 2025 criteria above but a quality performance score that is ≥ than 10th percentile of performance benchmark on ≥ 1 (of 4) APP Plus quality measure set outcome measures would allow shared savings (if otherwise eligible) at a lower rate that	Fails to meet 2025 criteria above but a quality performance score that is ≥ than 10th percentile of performance benchmark on ≥ 1 (of 4) APP Plus quality measure set outcome measures would allow shared savings (if otherwise eligible) at a lower rate that	Fails to meet 2025 criteria above but a quality performance score that is ≥ than 10th percentile of performance benchmark on ≥ 1 (of 4) APP Plus quality measure set outcome measures would allow shared savings (if otherwise eligible) at a lower rate that

Proposed APP Plus Quality Measure Set Reporting Requirements and Quality Performance Standard for PY 2025 and Subsequent PYs (Based on Table 33 in the rule with formatting modifications)			
	PY 2025	**PYs 2026 and 2027**	**PY 2028 and Subsequent PYs**
	is scaled by the ACO's health equity adjusted quality performance score	is scaled by the ACO's health equity adjusted quality performance score	is scaled by the ACO's health equity adjusted quality performance score
Quality Performance Standard is NOT Met	If an ACO (1) does not report any of the 5 eCQMs/ Medicare CQMs in the APP Plus quality measure set and (2) does not administer a CAHPS for MIPS survey, the ACO will not meet the quality performance standard or the alternative quality performance standard. The ACO will be ineligible to share savings and will owe maximum shared losses, if applicable.	If an ACO (1) does not report any of the 6 eCQMs/ Medicare CQMs in the APP Plus quality measure set and (2) does not administer a CAHPS for MIPS survey, the ACO will not meet the quality performance standard or the alternative quality performance standard. The ACO will be ineligible to share savings and will owe maximum shared losses, if applicable.	If an ACO (1) does not report any of the 8 eCQMs/ Medicare CQMs in the APP Plus quality measure set and (2) does not administer a CAHPS for MIPS survey, the ACO will not meet the quality performance standard or the alternative quality performance standard. The ACO will be ineligible to share savings and will owe maximum shared losses, if applicable.
* Facility-based scoring allows certain clinicians (e.g., pathologists) to be scored using their facilities' Hospital Value Based Purchasing Program results.			

f. Proposed APP Plus Measure Set

Tables 34, 35, and 36 of the rule show the proposed APP Plus quality measure set for MSSP ACOs for performance year 2025, performance years 2026 and 2027, and performance year 2028 and subsequent performance years, respectively. The below table consolidates information included in those tables.

Measures Included in APP Plus Quality Measure Set for MSSP ACOs				
Measure ID #	**Measure Title**	**Measure Type**	**Collection Type**	**Performance Years (PYs)**
321	CAHPS for MIPS Survey	Patient-Reported Outcome	CAHPS for MIPS Survey	PY 2025 and Subsequent PYs
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Outcome	Administrative Claims	PY 2025 and Subsequent PYs
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Outcome	Administrative Claims	PY 2025 and Subsequent PYs

Measures Included in APP Plus Quality Measure Set for MSSP ACOs				
Measure ID #	**Measure Title**	**Measure Type**	**Collection Type**	**Performance Years (PYs)**
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	Intermediate Outcome	eCQM /Medicare CQM	PY 2025 and Subsequent PYs
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	Process	eCQM /Medicare CQM	PY 2025 and Subsequent PYs
236	Controlling High Blood Pressure	Intermediate Outcome	eCQM/Medicare CQM	PY 2025 and Subsequent PYs
113	Colorectal Cancer Screening	Process	eCQM/Medicare CQM	PY 2025 and Subsequent PYs
112	Breast Cancer Screening	Process	eCQM/Medicare CQM	PY 2025 and Subsequent PYs
305	Initiation and Engagement of Substance Use Disorder Treatment	Process	eCQM/Medicare CQM	PY 2026 and Subsequent PYs
487	Screening for Social Drivers of Health	Process	eCQM/Medicare CQM	PY 2028 and Subsequent PYs
493	Adult Immunization Status	Process	eCQM/Medicare CQM	PY 2028 and Subsequent PYs

g. RFI: Survey Modes for the Administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey

CMS seeks public comment on the potential expansion of the survey modes of the CAHPS for MIPS Survey from a mail-phone protocol to a web-mail-phone protocol. See section IV.A.4.e(1)(e) of the rule for additional information on the RFI.

5. Providing for Option of Prepaid Shared Savings

a. Background

The 2023 PFS final rule created a new payment option for eligible Shared Savings Program ACOs entering agreement periods beginning on or after January 1, 2024, referred to as advance investment payment (AIP). Advance investment payments must be spent on one of the following categories: increased staffing, health care infrastructure, and the provision of accountable care for underserved beneficiaries, which may include addressing social determinants of health (42 CFR 425.630(e)(1)). Although advance investment payments are only available to new ACOs, many comments previously suggested that CMS should expand the eligibility criteria to include currently participating ACOs and high-revenue ACOs. CMS says it does not believe that it is appropriate to expand the eligibility criteria for advance investment payments at this time, because it still needs time to assess the impact of the new payment option; however, the agency cites evidence that investment in staffing, health care infrastructure, and accountable care for underserved beneficiaries could be valuable for all ACOs.

By encouraging ACOs to invest in new services that beneficiaries otherwise would not receive—like hearing, vision and dental services—beneficiaries could be encouraged to receive care from providers participating in an ACO and may ultimately receive improved care. For ACOs currently in MSSP that reinvest their shared savings payments, it could be more valuable to access those shared savings payments early in or throughout each performance year, instead of waiting months when earned shared savings payments are typically distributed.

The CMS Innovation Center tested this with more experienced ACOs in their programs (e.g., Next Generation ACO model). These ACOs found value in access to funding during the performance year, with almost all Next Generation ACOs using the funds to develop workflows informed by data analytics and clinical staff input and to support care management. The agency shares similar results from multiple Innovation Center ACO models and acknowledges that additional ACOs could benefit from expanded access to performance year funding that encourages investment in staffing, health care infrastructure, and additional services.

Rather than expanding eligibility to advance investment payments, CMS proposes to provide prepaid shared savings to certain existing ACOs, with standards for such payments proposed in new §425.640. This new payment option would provide prepaid shared savings to ACOs with a history of earning shared savings while participating in MSSP. These payments would be distributed on a quarterly basis and would be recouped from shared savings determined during the annual financial reconciliation cycle. If the ACO does not earn sufficient shared savings to offset the advanced payment, CMS may withhold or terminate the ACO's prepaid shared savings under proposed §425.640(h)(1)(iii).

Based on the previously cited evidence, CMS has determined that allowing ACOs access to funding earlier than currently available would improve the quality and efficiency of beneficiary care, therefore meeting the standard of section 1899(i)(3)(A) of the Act.[18] CMS intends to periodically reassess whether the payment of prepaid shared savings continues to improve the quality and efficiency of items and services furnished to Medicare beneficiaries without resulting in additional program expenditures. If it no longer satisfies the requirements of section 1899(i)(3), CMS would undertake additional notice and comment rulemaking to adjust the payment methodology to assure continued compliance with the statutory requirements.

b. Eligibility

CMS proposes to establish eligibility criteria for prepaid shared savings in §425.640(b), which requires an ACO to meet all of the following criteria:

- The ACO is a renewing ACO entering an agreement period beginning on January 1, 2026, or in subsequent years.
- The ACO must have received a shared savings payment for the most recent performance year that:

[18] Section 1899(i)(3)(B) of the Act requires CMS to determine that prepaid shared savings will not result in additional program expenditures. The addition of prepaid shared savings meets this standard because the eligibility criteria for prepaid shared savings have been selected to only permit ACOs that CMS estimates are most likely to earn shared savings to receive payments. In addition, CMS would be protected by the ACOs' repayment mechanisms in the event that an ACO does not earn shared savings, etc.

    - Occurred prior to the agreement period for which the ACO has applied to receive prepaid shared savings; and
    - CMS has conducted financial reconciliation.
- The ACO must have a positive prior savings adjustment as calculated per §425.658 at application disposition for the agreement period in which they would receive prepaid shared savings.
- The ACO does not have any outstanding shared losses or advance investment payments that have not yet been repaid to CMS after reconciliation for the most recent performance year for which CMS completed financial reconciliation.
- If the ACO received prepaid shared savings in the current agreement period or a prior agreement period, the ACO must have fully repaid the amount of prepaid shared savings received through the most recent performance year for which CMS has completed financial reconciliation.
- The ACO is participating in Levels C-E of the BASIC track or the ENHANCED track during the agreement period in which they would receive prepaid shared savings.
- The ACO has in place an adequate repayment mechanism in accordance with §425.204(f) that can be used to recoup outstanding prepaid shared savings.
- During the agreement period immediately preceding the agreement period in which the ACO would receive prepaid shared savings, the ACO:
    - Met the quality performance standard as specified under §425.512; and
    - Has not been determined by CMS to have avoided at-risk beneficiaries as specified under §425.316(b)(2).

CMS elaborates on many of these criteria, which were selected to allow only ACOs with a record of meeting the quality performance standard, not avoiding at-risk beneficiaries, and recent success in earning shared savings to receive prepaid shared savings. This is for the protection of both CMS and the ACOs, as CMS does not want to overestimate an ACO's ability to earn future shared savings and burden an ACO with debt that it would not be able to repay.

New ACOs would not be eligible for prepaid shared savings, as they do not have a recent performance history for estimating future performance. Many new ACOs are eligible to receive advance investment payments, which are not available to ACOs currently participating in the Shared Savings Program. Advance investment payments are more tailored to the needs of a new ACO as there is more flexibility in the use of funding, and advance investment payments do not need to be repaid in the event that the ACO does not earn shared savings.

As CMS intends to provide prepaid shared savings to ACOs if they improve and maintain performance and continue to see success in the program on an annual basis, ACOs that are not initially eligible would have the option to participate in the prepaid shared savings payment option in future years if they demonstrate a more recent history of success in the program and meet the other eligibility criteria. These criteria provide an additional incentive for ACOs to improve their performance. CMS would also continue to review the eligibility criteria over time and may expand eligibility in future years.

To standardize timelines for payment, spending and recoupment of prepaid shared savings, ACOs would only be eligible for prepaid shared savings if they renew to begin a new agreement

period. The proposed policies for the calculation, spending and recoupment of prepaid shared savings allow for up to five years for ACOs to receive, spend and repay the funding through earned shared savings.

A new paragraph in §425.100(e) would establish that an ACO may receive prepaid shared savings if it meets the criteria under §425.640(b).

c. Application Procedure and Contents

CMS proposes to establish the process for an ACO to apply for prepaid shared savings in §425.640(c), under which an ACO must submit supplemental application information sufficient for CMS to determine whether the ACO is eligible. The application cycle for prepaid shared savings would be conducted as part of the MSSP application process, with instructions and timelines published on the MSSP website. The initial application cycle to apply for prepaid shared savings would be for a January 1, 2026, start date. CMS will provide additional information regarding the process through subregulatory guidance.

CMS would provide preliminary information to the applicant ACO about its eligibility to receive prepaid shared savings during the Phase 1 application cycle requests for information, and a final determination about its eligibility to receive prepaid shared savings at the time of final application dispositions. For example, for ACOs applying in 2025 for an agreement period beginning in 2026, CMS would provide preliminary information identifying whether an ACO is likely to earn shared savings in the 2024 performance year and have a positive prior savings adjustment at application disposition.

Under proposed §425.640(d)(1), an ACO would be required to submit a spend plan as part of its application for prepaid shared savings, which must describe how the ACO would spend the prepaid shared savings during the first performance year of the agreement period with prepaid shared savings, including (1) direct beneficiary services that would be provided to ACO beneficiaries; and (2) investments that would be made in the ACO with prepaid shared savings. ACOs must also include their communication strategy for informing both CMS and any impacted beneficiaries if the ACO will no longer be providing any direct beneficiary services (as described in greater detail below) that had previously been provided by the ACO using prepaid shared savings. ACOs would be able to limit the distribution of direct beneficiary services to subgroups of assigned beneficiaries, including those with specific medical conditions or specific socioeconomic needs, but would be required to attest that they will not discriminate on the basis of race, color, religion, sex, national origin, disability, or age with respect to their use of prepaid shared savings.

At §425.640(d), CMS proposes to review the information submitted in the ACO's prepaid shared savings application to determine whether it meets the criteria for prepaid shared savings and would approve or deny the application accordingly, simultaneously with the ACO's Shared Savings Program renewal application. CMS highlights other provisions that are discussed in greater detail in their respective sections below.

Public reporting requirements would be updated for ACOs to publicly report:

- The total amount of prepaid shared savings received from CMS for each performance year;
- The ACO's spend plan; and
- An itemization of how the prepaid shared savings were actually spent during each performance year, including
    - Expenditure categories,
    - Dollar amounts spent on the various categories,
    - Information about which groups of beneficiaries received direct beneficiary services that were purchased with prepaid shared savings and investments that were made in the ACO with prepaid shared savings,
    - How these direct beneficiary services were provided to beneficiaries and how the direct beneficiary services and investments supported the care of beneficiaries,
    - Any changes to the spend plan as submitted under §425.640(d)(2) (if applicable), and
    - Such other information as may be specified by CMS.

CMS will also make this data publicly available through a public use file and expects to use the submitted data as the template that ACOs can use to populate their public reporting webpage early in each performance year, to minimize administrative burden for ACOs.

d. Allowable and Prohibited Uses of Prepaid Shared Savings

In §425.640(e), CMS proposes to specify how an ACO may use prepaid shared savings, with flexibility to use payments consistent with broad allowable uses, but also with restrictions on the amount of total annual prepaid shared savings that can be spent on each category of spending. Because financially successful ACOs are likely to have already made significant investments in staffing and health care infrastructure, CMS intends to encourage ACOs receiving prepaid shared savings to invest in direct beneficiary services not already offered by the ACO, such as vision, hearing and dental services. However, staffing and health care infrastructure are still important expenses that can have positive impacts. Thus, CMS intends to allow ACOs to use some of their prepaid shared savings to invest in these areas. For each performance year, ACOs would be permitted to use up to 50 percent of their estimated annual prepaid shared savings on staffing and health care infrastructure and up to 100 percent on direct beneficiary services (proposed §425.640(e)(1)). ACOs must use at least 50 percent of their prepaid shared savings on direct beneficiary services.

CMS then lists permitted uses for each of these terms: staffing, health care infrastructure, and direct beneficiary services. For example, direct beneficiary services could include cost sharing support as well as beneficiary meals, nutrition support, tenancy support and sustaining services, housing assistance, utility support, caregiver support services, services to address social isolation, home visits, transportation services, home or environmental modifications like air conditioners, bathroom safety devices, personal emergency response systems or medical alert systems, and vision, hearing or dental care directly provided by ACO providers/suppliers or covered under a health insurance plan purchased by the ACO on behalf of the beneficiary.

In §425.640(e)(2), CMS proposes that an ACO may not use prepaid shared savings for any expense other than those allowed under paragraph (e)(1). Prohibited uses would include management company or parent company profit, performance bonuses, provision of medical services covered by Traditional Medicare, cash or cash equivalent payments to patients, and items or activities unrelated to the management and operations of an ACO or care of beneficiaries. An ACO participating in Levels C-E of the BASIC track or the ENHANCED track may not use any prepaid shared savings to pay back any shared losses that it would have incurred.

CMS encourages, at length, ACOs to coordinate with a community-based organization (CBO) to provide direct beneficiary services that address unmet social needs, including food insecurity and transportation problems. The agency points to the 2023 PFS proposed rule (87 FR 46102), where CBOs are defined as public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations, including community-action agencies, housing agencies, area agencies on aging, or other non-profits that apply for grants to perform social services. If an ACO works with a CBO to provide these types of services, as reflected in its plan to address the needs of its population, CMS would consider them in compliance with the existing regulatory requirement at §425.112(b)(2)(iii)(A), which requires an ACO to describe how it intends to partner with community stakeholders to improve the health of its population.

CMS also proposes (§425.640(f)(6)) to allow ACOs receiving prepaid shared savings to request a smaller quarterly payment amount. The agency provides an example that if an ACO is eligible for annual prepaid shared savings amount of $4 million for the year, the ACO could spend up to $2 million of that on staffing and health care infrastructure; on the other hand, the ACO is permitted to spend its entire prepaid shared savings amount on direct beneficiary services. The ACO may request a lower quarterly payment of $500,000 that results in the ACO only receiving $2 million over the full performance year, thus reducing the amount the ACO can spend on staffing and healthcare infrastructure—in this example, to $1 million.

e. Calculation of Prepaid Shared Savings

The proposed policies on the calculation and distribution of the prepaid shared savings payments are intended to balance (1) the benefit for the ACOs of receiving funding earlier, (2) the risk of overpayment both for CMS and the ACO, and (3) the requirement that prepaid shared savings do not result in additional program expenditures. A new §425.640(f)(2) specifies the maximum quarterly amount (§425.640(f)(2)).

CMS would notify in writing each ACO of the following:

- CMS' determination of the amount of prepaid shared savings;
- The ACO's right to request reconsideration review;
- If CMS does not make any prepaid shared savings payment, the reason(s) why and the ACO's right to request reconsideration review;
- Prior to each quarterly payment, CMS' calculation of the ACO's quarterly prepaid shared savings amount, coinciding with the timing of existing report packages sent to ACOs for informational purposes—

- December (after initial assignment prior to a given performance year),
- May (after quarter 1 assignment for a given performance year), and
- August (after quarter 2 assignment for a given performance year).[19]

An ACO's maximum quarterly prepaid shared savings payment would be based on a prepaid shared savings multiplier, adjusted by several factors explained below and multiplied by one-fourth of the ACO's assigned beneficiary person years:

- Prepaid shared savings multiplier would be the simple average of per capita savings or losses generated by the ACO during the two most recent performance years that have been financially reconciled at the time of the ACO's renewal application disposition, which constitute benchmark year (BY) 1 and BY2 of the agreement period in which the ACO may receive prepaid shared savings ("current agreement period," hereafter).
  - BY3 would be excluded from the calculation of an ACO's average per capita savings or losses because the performance year that constitutes BY3 of the ACO's current agreement period would not have been financially reconciled at the time of the ACO's application disposition.
- Per capita savings for each performance year would be a quotient—specifically, the ACO's updated benchmark expenditures minus total performance year expenditures divided by performance year assigned beneficiary person years.
  - All savings generated during each of the two performance years would be included, not just savings that met or exceeded the ACO's minimum savings rate (MSR).

A proration factor would be applied to the prepaid shared savings multiplier to account for situations where an ACO's assigned beneficiary population is larger in BY1 and BY2 when calculated using the ACO's certified participant list and assignment methodology for a given performance year within the current agreement period, as compared to the ACO's assigned beneficiary population when the ACO was reconciled for the performance years that constitute BY1 and BY2 of the current agreement period.

To apply this proration factor, CMS would calculate the ratio between:

- The ACO's average assigned beneficiary person years for the two performance years that constitute BY1 and BY2 for the ACO's current agreement period (regardless of whether these performance years occurred over one or multiple prior agreement periods, which would occur if the ACO early renews immediately before the current agreement period), and
- The average assigned beneficiary person years in BY1 and BY2 for the ACO's current agreement period calculated using the ACO's certified ACO participant list and assignment methodology for a given performance year within the current agreement period.

Increases in the size of the ACO's assigned beneficiary population during the current agreement period would therefore result in a ratio less than 1 (as shown in Step 2 of the example in Table 37

[19] Notice regarding the first and second quarterly payments would be provided in December of the immediately preceding year. Subsequent notices regarding the third and fourth quarterly payments that an eligible ACO would receive in a given performance year would then be provided in May and August, respectively.

of the proposed rule, reproduced below), while decreases in the assigned beneficiary population would result in a ratio greater than 1. This ratio would be capped at 1 to avoid increasing the adjusted prepaid shared savings multiplier if the average number of beneficiaries assigned to the ACO across the 2 benchmark years of its current agreement period is lower than the average number of beneficiaries assigned during the 2 performance years that constitute BY1 and BY2. Prorating for growth in assignment would ensure that the prepaid shared savings amount does not exceed the amount of cumulative savings generated by the ACO during the performance years that constitute BY1 and BY2 for its current agreement period.

Under new §425.640(f)(3)(ii), CMS would redetermine this proration factor for the second and each subsequent performance year during the term of the current agreement period.

Under new §425.640(f)(2)(iv), CMS would also apply a sharing rate scaling factor of 50 percent. This would be similar to the scaling factor applied under §425.658(c)(1)(i) when calculating the prior savings adjustment (applicable to agreement periods beginning on or after January 1, 2024, as finalized in the CY 2023 final rule (87 FR 69899-69915)). This would take into account the sharing rate used in determining the shared savings payment the ACO earned under the agreement period immediately before it would receive prepaid shared savings. CMS says 50 percent represents an appropriate multiplier because it represents a middle ground between the maximum sharing rate of 75 percent under the ENHANCED track and the lower sharing rates available under the BASIC track.

The prepaid shared savings multiplier would then be the lesser of the financial risk scaling factor and 5 percent of national per capita expenditures for BY2 assignable beneficiaries. Under new §425.640(f)(2)(v)(A), the financial risk scaling factor would be equal to 2/3, in order to mitigate financial risk to the Medicare Trust Funds and to ACOs by reducing the possibility that an ACO's prepaid shared savings payments exceed the ACO's actual earned shared savings. The financial risk scaling factor enables CMS to account for a scenario in which an ACO earned zero per capita savings in BY3 of the current agreement period, which is necessarily excluded from the calculation of an ACO's average per capita savings or losses, as mentioned previously. By multiplying an ACO's average per capita savings or losses across BY1 and BY2 by a financial risk scaling factor equal to 2/3, CMS is imposing a reduction on the prepaid shared savings multiplier by assuming that it would have been possible for an ACO to have not earned any per capita savings in BY3. This reduces the probability of distributing excessive prepaid shared savings, which could result in ACOs accruing debt to CMS that they are unable to repay, etc.

To calculate the maximum quarterly prepaid shared savings payment, CMS proposes under new §425.640(f)(4) to multiply one-fourth of the prorated, adjusted, and capped prepaid shared savings multiplier by the ACO's assigned beneficiary person years for the latest available assignment list for a given performance year within the current agreement period. This would reflect the latest available assigned beneficiary person years, similar to the AIP quarterly payment calculation at §425.630(f) (87 FR 69797)). CMS would use assigned beneficiary person year values provided to ACOs in annual and quarterly informational reports.

The agency reviews its ACO assignment calculations and data reporting, detailing how they would apply in calculating assigned beneficiary person years. CMS provides an example that a

year-to-date person years value of 1,500 with quarter 1 informational reports would be annualized by multiplying 1,500 by 4. A year-to-date person years value of 3,000 with quarter 2 information reports would be annualized by multiplying 3,000 by 2. The annualized number would then be divided by 12.[20] CMS also walks through specific exceptional cases addressed by the proposed rule, designed primarily to avoid excessive distribution of prepaid shared savings that ACOs might have to repay.

Similarly, CMS also proposes in new §425.640(f)(3) to account for certain changes to the values used in calculating the prepaid shared savings multiplier as a result of issuance of a revised initial determination of financial performance under §425.315. For example, for the first performance year in the current agreement period, the ACO's prepaid shared savings multiplier would be recalculated for changes in per capita shared savings or losses for the performance years that constitute BY1 or BY2 and that are used in the calculation of the prepaid shared savings multiplier as a result of issuance of a revised initial determination under §425.315. For the second and each subsequent performance year during the term of the current agreement period, the ACO's prepaid shared savings multiplier would be recalculated due to redetermining the proration factor for the addition and removal of ACO participants or ACO providers/suppliers in accordance with §425.118(b), for a change to the ACO's beneficiary assignment methodology selection under §425.226(a)(1), for a change to the beneficiary assignment methodology specified in subpart E of this part, and for changes in per capita shared savings or losses for the performance years that constitute BY1 or BY2 and that are used in the calculation of the prepaid shared savings multiplier as a result of issuance of a revised initial determination under §425.315.

In the proposed rule, CMS then reiterates the steps for the calculation of the maximum quarterly prepaid shared savings payment, along with Table 37 (reproduced below) that presents a hypothetical example to demonstrate how the prepaid shared savings calculation would work in practice.

Table 37. Calculation of Maximum Quarterly Prepaid Shared Savings Payment

Step 1: Calculate prepaid shared savings multiplier	Per capita savings generated in the two performance years that constitute BY1 and BY2 for the ACO's current agreement period beginning January 1, 2022 PY 2019: $350 PY 2020: $400 Multiplier: Simple average of the per capita savings across BY1 and BY2 ($350 + $400) / 2 = $375

[20] This step of dividing by 12 was not included in this portion of the preamble (p. 786, public inspection version) but was added by HPA for clarity and consistency with CMS' policy generally, as mentioned in the more detailed description later in the rule (footnote 500, p. 810)—that is, calculating person years by taking the sum of the person months and dividing by 12.

Step 2: Prorate the prepaid shared savings multiplier	Assigned person years from the performance years that constitute BY1 and BY2 for the ACO's current agreement period beginning January 1, 2022: PY 2019: 6,000 PY 2020: 7,000 Assigned person years for BY1 and BY2 of current agreement period (determined using certified ACO participant list for the current performance year of PY 2022): BY 2019: 8,000 BY 2020: 7,500 Proration factor: Ratio between the ACO's average person years in the performance years that constitute BY1 and BY2 and the average person years in BY1 and BY2, excluding years for which the ACO was not reconciled, capped at 1. Apply the proration factor to the prepaid shared savings multiplier: [(6,000 + 7,000)/2] / [(8,000 + 7,500)/2] x $375 = $314.52 [HPA note: In this example, the proration factor would be approximately 0.84.]
Step 3: Adjust the prorated prepaid shared savings multiplier for financial risk and sharing rate	Shared savings scaling factor: (0.5) Financial risk scaling factor: (2/3) Apply the shared savings scaling factor and the financial risk scaling factor to the prorated prepaid shared savings multiplier: $314.52 x (0.5) x (2/3) = $104.84
Step 4: Cap the prorated, adjusted prepaid shared savings multiplier	National assignable per capita FFS expenditures for assignable beneficiaries in BY2: $10,000 Cap: 5 percent of national assignable per capita FFS expenditures for assignable beneficiaries in BY2 0.05 * $10,000 = $500
Step 5: Determine the maximum prepaid shared savings payments for the applicable quarter	Assigned beneficiary person years derived from the ACO's latest available assignment list: 8,500. Total prepaid shared savings payments for the applicable quarter: Product of one-fourth of the prorated, adjusted, capped prepaid shared savings multiplier and the assigned beneficiary person years derived from the ACO's latest available assignment list. ($104.84/4) x 8,500 = $222,785

The ACO's maximum quarterly prepaid shared savings payments would set a ceiling on the amount of quarterly prepaid shared savings that an ACO could receive. ACOs may request less than the full amount they may be eligible to receive. Before each performance year, ACOs would notify CMS of the amount of prepaid shared savings they want to receive in the first quarter (under the maximum quarterly prepaid shared savings amount), which will be used to determine the total amount of prepaid shared savings the ACO will use to budget for that performance year. The estimated *annual* prepaid shared savings amount would be calculated by multiplying the first *quarterly* payment amount by four. If an ACO's maximum quarterly payments decrease over the performance year and result in the ACO receiving less than the estimated annual prepaid shared savings amount, the ACO would not be subject to compliance actions solely because it spent more than 50 percent of the actual annual amount of prepaid shared savings on staffing and healthcare infrastructure, as long as it did not spend more than 50 percent of the *originally* estimated annual amount on staffing and healthcare infrastructure.

f. Duration, Frequency and Withholding or Termination of Prepaid Shared Savings Payments

Duration and Frequency. Due to its conservative calculations, CMS anticipates the vast majority of ACOs receiving prepaid shared savings would not be overpaid via those prepaid savings and thus would ultimately have their earned shared savings fully repay the share that was prepaid. ACOs would receive quarterly prepaid shared savings payments for the entirety of the ACO's agreement period unless withheld or terminated pursuant to §425.640(h).

If CMS withholds or terminates a quarterly payment pursuant to paragraph (h), the ACO would not receive additional or catch-up payments if quarterly prepaid shared savings payments are later resumed. As discussed later, prepaid shared savings payments would generally be withheld when CMS has information that the ACO may not generate sufficient earned shared savings to repay the prepaid shared savings or has other MSSP compliance issues. Once prepaid shared savings payments are withheld, if an ACO earns shared savings in a future year, then prepaid shared savings can resume at the time of the next scheduled quarterly payment, but catch-up payments would not be provided.

Withholding and Termination. CMS proposes that it may withhold or terminate quarterly prepaid shared savings payments under a variety of specified circumstances, many of which relate to instances where CMS would be concerned that the ACO has not or will not meet the standards for the use prepaid shared savings or is likely to lack the ability to repay prepaid shared savings. CMS may also withhold quarterly payments if an ACO fails to earn enough shared savings in a performance year to fully repay the prepaid shared savings. If an ACO has unspent funding at the end of their agreement period, that funding must be repaid to CMS pursuant to proposed §425.640(e)(3).

Specifically, at §425.640(h)(1), CMS could withhold or terminate prepaid shared savings for any of the following reasons:

- The ACO fails to comply with any of the prepaid shared savings requirements of §425.640;
- The ACO meets any of the grounds for ACO termination in §425.218(b);
- The ACO fails to earn sufficient shared savings from a performance year to repay the prepaid shared savings they received during that performance year;
- CMS determines that the ACO is not expected to earn shared savings in a performance year, based on a rolling 12-month window of beneficiary claims data or year-to-date beneficiary claims data;
- The ACO falls below 5,000 assigned beneficiaries;
- The ACO fails to spend the majority of prepaid shared savings they receive in a performance year; or
- The ACO requests that CMS withhold a future quarterly payment

CMS proposes at §425.640(h)(2) that it must terminate an ACO's prepaid shared savings if:

- The ACO fails to maintain an adequate repayment mechanism in accordance with §425.204(f); or

- The ACO fails to meet the quality performance standard as specified under §425.512 or is subject to a pre-termination action after CMS determined the ACO avoided at-risk beneficiaries as specified under §425.316(b)(2).

Under §425.640(h)(4), CMS may immediately terminate an ACO's prepaid shared savings for any of the reasons above without taking any of the pre-termination actions that generally apply to ACOs in existing §425.216.

If CMS predicts that an ACO would not earn shared savings in its current performance year, quarterly prepaid shared savings may be withheld until the ACO generates earned shared savings in the future. Immediate termination of prepaid shared savings without a possibility of resumption of payments during that agreement period would generally be invoked only in cases of serious noncompliance, such as deliberately spending prepaid shared savings on a prohibited use.

g. Monitoring ACO Eligibility for and use of Prepaid Shared Savings

In §425.316(f)(1), CMS proposes to monitor ACOs receiving prepaid shared savings for compliance and to determine whether it would be appropriate to withhold or terminate an ACO's prepaid shared savings for the reasons above. For the first performance year of the current agreement period, the agency would monitor the ACO's use of prepaid shared savings by comparing the anticipated spending as set forth in the spend plan submitted with an ACO's application against its actual spending. ACOs would be required to submit a revised spend plan with updated anticipated spending annually, as well as annually report their actual expenditures to CMS and on their public reporting webpage. The reported annual spending must include any expenditures of prepaid shared savings on items not identified in the spend plan. If an ACO uses prepaid shared savings for uses not permitted, CMS would require them to reallocate the funding to a permitted use and may take compliance action, including withholding or terminating payments.

CMS believes that transparency of information in health care enables more informed patient choice, offers incentives and feedback that help improve the quality and lower the cost of care, and improves oversight with respect to program integrity. Thus, CMS is proposing to modify §425.308 to require that an ACO publicly report information annually regarding prepaid shared savings on its public reporting webpage. Specifically, under proposed new §425.308(b)(10), for each performance year, an ACO would be required to report the following (in a standardized format specified by CMS):

- Its spend plan for each performance year,
- The total amount of prepaid shared savings received, and
- An itemization of how any prepaid shared savings were actually spent during each year, including—
    - Expenditure categories,
    - Dollar amounts spent on the various categories,
    - Information about which beneficiaries received direct beneficiary services that were purchased with prepaid shared savings and investments that were made in the ACO with prepaid shared savings,

- Any changes to the spend plan, and
- Such other information as may be specified by CMS.

This itemization would include expenditures not identified or anticipated in the ACO's submitted spend plan, and any amounts remaining unspent. Under §425.640(i), ACOs would also be required to report this information directly to CMS.

h. Recoupment of Prepaid Shared Savings

Prepaid shared savings are an advance of the shared savings payments an ACO is expected to earn. CMS proposes to recoup prepaid shared savings that ACOs are unable to fully repay through their earned shared savings. Under new §425.640(g)(1), if there are insufficient shared savings to recoup the prepaid shared savings, CMS would pause paying future prepaid shared savings payments and carry forward the remaining balance owed to subsequent performance year(s) in which the ACO achieves shared savings. Additional provisions (§425.640(g)(2)) address circumstances where the amount of shared savings is revised by CMS.

Under §425.640(g)(3), if an ACO has an outstanding balance of prepaid shared savings after the calculation of shared savings or losses for the final performance year of an agreement period, the ACO must repay any outstanding amount of prepaid shared savings it received in full upon request from CMS. CMS would provide written notification to the ACO of the amount due, which the ACO must pay no later than 90 days after the receipt of notification. Otherwise, CMS would recoup that amount from the ACO's repayment mechanism established under existing §425.204(f).

As an example, if an ACO received $300,000 in prepaid shared savings payments and earned shared savings of $500,000 for the first performance year, CMS would recoup $300,000 in prepaid shared savings payments and make $200,000 in reconciliation shared savings payments to the ACO. Alternatively, if an ACO received $300,000 in prepaid shared savings and earned shared savings of $200,000 for the first performance year, CMS would recoup only $200,000 in prepaid shared savings payment and not make a reconciliation shared savings payment to the ACO; the ACO would have future prepaid shared savings payments placed on hold, and the outstanding balance of $100,000 would be carried forward, to be recouped in a future performance year in which the ACO achieves shared savings. However, if an ACO does not earn sufficient shared savings in all five performance years of its agreement period, CMS would recoup the outstanding balance directly from the ACO under new §425.640(g)(3). If the ACO fails to repay the funding to CMS, the agency would recoup the outstanding balance from the ACO's repayment mechanism.

If an ACO or CMS terminates its participation agreement during the agreement period, the ACO must repay all outstanding prepaid shared savings received in full, with the same 90-day requirement mentioned above. CMS also includes provisions in case an ACO enters into proceedings relating to bankruptcy.

i. OIG Safe Harbor Authority

CMS expects to make a determination that the antikickback statute safe harbor for CMS-sponsored model patient incentives (§1001.952(ii)(2)) is available to protect patient incentives that may be permitted under this rule. That is, the CMS-sponsored models' safe harbor would be available to protect direct beneficiary services provided to beneficiaries through the prepaid shared savings payment option. To conform, CMS proposes to add a new paragraph (d) to §425.304, noting that CMS has determined that the federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives is available.

6. Advance Investment Payment Policies

a. Proposal to Allow ACOs Receiving Advance Investment Payments to Voluntarily Terminate Payments while Continuing Participation in the Shared Savings Program

As previously mentioned, beginning January 1, 2024, CMS implemented AIP in MSSP, codified at §425.630. Currently, there are no regulations for an ACO that seeks to voluntarily terminate receipt of AIP but wishes to remain in MSSP. While CMS expects this to be uncommon, since advance investment payments are a voluntary payment option,[21] ACOs should be able to decline further participation. To accommodate such voluntary terminations, CMS proposes to modify program regulations at §425.630(g) and (h) accordingly, effective January 1, 2025.

Under updated §425.630(g), ACOs opting to voluntarily terminate from the advance investment payment option would be required to return any outstanding advance investment payments to CMS. Upon an ACO notifying CMS that it wants to terminate, CMS would then provide a written notification to the ACO of the total amount of recoupment due, which the ACO must repay within 90 days of the receipt of the notification.

b. Proposal to Recoup Advance Investment Payments when CMS Terminates the Participation Agreement of an ACO

Under current AIP regulations, there is no clear pathway for CMS to recoup outstanding advance investment payments if CMS terminates an ACO's participation agreement in accordance with §425.218(b). Thus, CMS proposes to add new §425.630(g)(6) to require ACOs to repay any outstanding AIP in the event that CMS terminates the ACO's Shared Savings Program participation agreement.

Upon the termination of their Shared Savings Program participation agreement, the ACO's AIP would cease immediately, CMS would provide the ACO with written notification of the total amount due for the full recoupment, and the ACO must repay within 90 days after receipt of the notification. If an ACO fails to fully repay the AIP received, CMS would carry forward any remaining balance owed to subsequent performance year(s) in which the ACO achieves shared savings, including in any performance year(s) in a subsequent agreement period. Conforming edits to §425.630(g)(3) would allow CMS to recoup more than the amount of shared savings

[21] An ACO may have justified business reasons for terminating receipt of AIP, such as to enter a CMS Innovation Center model that excludes ACOs receiving AIP.

earned by an ACO in a particular performance year in the event that an ACO or CMS terminates an ACO from the advance investment payment option or MSSP as a whole.

If finalized, these proposals would be effective beginning January 1, 2025.

7. Financial Methodology

a. Overview

In this section of this proposed rule, CMS is proposing modifications to the MSSP financial methodologies in order encourage participation by removing barriers for ACOs serving underserved communities and providing greater specificity on how CMS would perform certain financial calculations. Specifically, CMS proposes creating a health equity benchmark adjustment (HEBA) to potentially provide an upward adjustment to an ACO's historical benchmark based on the proportion of beneficiaries it serves who are dually eligible for both Medicare and Medicaid (duals) or enrolled in the Medicare Part D low-income subsidy (LIS).

In addition, CMS would establish a calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts, upon reopening a payment determination pursuant to §425.315(a). This would establish an approach to identify significant, anomalous, and highly suspect (SAHS) billing activity in 2024 or subsequent years and would specify how CMS would exclude payment amounts from expenditure, revenue, and historical benchmark calculations where the SAHS billing activity is identified.

The agency seeks comment on a financial model that would allow for higher risk and potential reward than currently available under the ENHANCED track while still meeting statutory requirements and other considerations. CMS is also proposing certain modifications for clarity and consistency in provisions on calculation of the ACO risk score growth cap in risk-adjusting the benchmark each performance year and the regional risk score growth cap in calculating the regional component of the three-way blended benchmark update factor.

b. Health Equity Benchmark Adjustment

Background. CMS reviews its statutory authority to establish and adjust ACO benchmarks under MSSP. The agency then reviews some regulatory changes made under that authority.

CMS further reviews how, under the benchmarking methodology for agreement periods beginning on or after January 1, 2024, it calculates two adjustments to the historical benchmark—a regional adjustment and a prior savings adjustment. CMS determines whether to apply the regional adjustment, prior savings adjustment, or no adjustment.

In great detail, the agency describes its current steps in establishing ACO benchmarks, summarized as follows:

- *Step 1*: Calculate the capped regional adjustment to the historical benchmark as a single dollar value, based on the ACO's regional service area expenditures, separately for the

four subgroups of ESRD, disabled, aged duals, and aged non-duals. A number of potential limits (caps) on positive and negative adjustments may apply.

- *Step 2*: Calculate the capped prior savings adjustment to account for savings generated in the 3 years prior to the start of the ACO's current agreement period, for renewing or re-entering ACOs that were reconciled for one or more performance years during this period.
- Step 3: Determine the final adjustment to the benchmark by comparing the regional adjustment and the prior savings adjustment.
    - If an ACO is not eligible to receive a prior savings adjustment but the regional adjustment (expressed as a single value) is positive, the ACO's adjustment will be equal to the positive regional adjustment amount, calculated and applied separately for the four subgroups mentioned above.
    - If an ACO is not eligible to receive a prior savings adjustment and the regional adjustment (expressed as a single value) is negative or zero, the ACO will not receive an adjustment.
    - If an ACO is eligible to receive a prior savings adjustment and the regional adjustment (expressed as a single value) is positive, the ACO will receive an adjustment equal to the higher of those two amounts, calculated and applied separately for the four subgroups mentioned above.
    - If an ACO is eligible to receive a prior savings adjustment and the regional adjustment (expressed as a single value) is negative or zero, the ACO will receive an adjustment to its benchmark equal to the prior savings adjustment, calculated and applied separately for the four subgroups mentioned above.

CMS then reminds readers of its efforts in the last two PFS rules to advance health equity, including the establishment of the health equity adjustment to an ACO's MIPS quality performance category score; the availability of AIP to eligible new, low-revenue ACOs entering a new agreement period beginning on or after January 1, 2024; and changes to the benchmarking methodology to facilitate participation by ACOs serving medically complex or underserved beneficiaries.

The 2023 PFS final rule included responses to CMS' RFI on addressing health equity through ACO benchmarking. The vast majority of commenters expressed support for exploring methodologies to address health equity via benchmarking changes, with many noting that benchmark adjustments could be an effective tool to redirect resources to ACOs serving underserved communities. Multiple commenters commented specifically on the HEBA approach in the Innovation Center's ACO Realizing Equity, Access, and Community Health (REACH) Model, expressing support for a similar methodology in MSSP. CMS has now determined that it would be timely to implement a HEBA into the MSSP's benchmarking methodology, to ensure benchmarks continue to serve as a reasonable baseline when ACOs serve high proportions of beneficiaries who are members of underserved communities and to incentivize ACOs to provide coordinated care to beneficiaries in those communities. CMS says this is likely to encourage more participation in MSSP by ACOs that serve beneficiaries who are members of rural and underserved communities by allowing them to participate with potentially higher benchmarks and thus increasing the likelihood that earn shared savings.

Proposed Revisions. CMS proposes a HEBA for ACOs in agreement periods beginning on or after January 1, 2025. The proposed HEBA would offer a third method of upwardly adjusting an ACO's historical benchmark, in addition to the existing regional adjustment and prior savings adjustment. The HEBA's upward adjustment to the historical benchmark is designed to benefit ACOs serving larger proportions of beneficiaries from underserved communities and receiving lower regional adjustments, lower prior savings adjustments, or no positive adjustment at all.

Under proposed §425.652(a)(8)(ii), an ACO would receive the highest of the positive adjustments for which it is eligible—the regional adjustment, prior savings adjustment, or HEBA. CMS notes that, if finalized, the proposed prepaid shared savings option (described above in section III.G.5) would operate "synergistically" with the proposed HEBA, in that ACOs that have been successful in earning shared savings while serving larger proportions of beneficiaries from underserved communities would have additional capabilities through prepaid shared savings to address the unmet health-related social needs of the beneficiaries they serve and may have higher benchmarks due to the HEBA.

If an ACO is not eligible to receive a prior savings adjustment or a HEBA, and the regional adjustment (expressed as a single value) is negative or zero, the ACO would not receive an adjustment.

CMS proposes to calculate the HEBA as the product of the HEBA scaler and the proportion of the ACO's assigned beneficiaries who are duals or enrolled LIS. The HEBA scaler would be the difference between the following two per capita dollar values:

- 5 percent of national per capita expenditures for Parts A and B services under the original Medicare FFS program in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary, expressed as a single value by taking a person year weighted average of the Medicare enrollment type-specific values for the previously mentioned four subgroups; and
- The highest of—
    - The regional adjustment (expressed as a single value),
    - The prior savings adjustment, or
    - No adjustment, in the case where the regional adjustment is negative and the ACO is not eligible for the prior savings adjustment.

This approach would ensure that the value of the HEBA itself cannot exceed 5 percent of national assignable per capita expenditures using the ACO's BY3 enrollment proportions, similar to the caps applied to the regional adjustment and to the prior savings adjustment.

CMS reiterates that, for this proposed health equity benchmark adjustment, beneficiaries from underserved communities would be identified as those who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid. The proportion of the ACO's assigned beneficiaries who are enrolled in LIS or dually eligible would be based on the ACO's performance year assigned population. Because a higher proportion of assigned beneficiaries in LIS or dually eligible would result in a higher HEBA, using the performance year assigned population is expected to incentivize ACOs to provide coordinated care to beneficiaries who are members of underserved communities.

CMS would provide ACOs with a preliminary calculation of the HEBA near the start of their agreement period, when final historical benchmarks are determined, using the ACO's BY3 assigned population and the proportion who are enrolled in LIS or dually eligible. This would be updated at the time of financial reconciliation for the performance year to reflect the ACO's performance year-assigned population.

ACOs with less than 20 percent of their aligned beneficiaries enrolled in LIS or dually eligible would be ineligible for a HEBA. CMS states that the HEBA is intended for ACOs serving higher proportions of beneficiaries who are members of underserved communities and, based on data from 2022, the average proportion of ACO-assigned beneficiaries enrolled in LIS or dually eligible was roughly 15 percent. Thus, ACOs meeting the threshold of 20 percent are serving a larger-than-average proportion of beneficiaries from underserved communities.

Simulation analysis based on 456 ACOs using historical benchmark data from 2023 indicates that 20 ACOs would receive a HEBA greater than either the prior savings adjustment or regional adjustment. With the HEBA applied, the average increase to historical benchmarks among these 20 ACOs would be $230 per capita, which corresponds to an average increase of 1.57 percent to their historical benchmarks. Tables 38 through 40 (not reproduced here) present hypothetical examples of how the HEBA would work.

The changes described in this section would be implemented through revisions to §425.652, the addition of §425.662, and conforming changes to § 425.658(d).

In combination with the proportion of ACO-assigned beneficiaries who are enrolled in the LIS or dually eligible, **CMS is seeking comment** on including the the Area Deprivation Index (ADI) to affect the HEBA. For example, similar to how the ADI is used in the underserved multiplier as part of the health equity adjustment to an ACO's MIPS Quality performance category score, CMS is considering, to determine eligibility for and the amount of any HEBA, taking the higher of either the proportion of the ACO's assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85 or the proportion of the ACO's assigned beneficiaries who are enrolled in LIS or dually eligible for both Medicare and Medicaid. CMS will explore how best to incorporate geographic parameters into Shared Savings Program benchmark adjustments, informed by the current use of the ADI in other health equity provisions of the Shared Savings Program. CMS will also consider results from the Innovation Center's ACO REACH Model, which is testing the use of the ADI as a component of that model's HEBA. By using ADI, the proposed MSSP HEBA would more closely align with existing Shared Savings Program policies to advance health equity and the calculation of the amount of quarterly advance investment payments made available to eligible new, low revenue ACOs.

Additionally, recent analyses have found that the ADI weights two variables (median home value and median income) higher relative to the weights associated with the other 15 variables in the index. In many indexes, variables are standardized to the same range for ease of comparison, prior to incorporation into the index. The ADI does not standardize its variables; median home value and median income are measured on their local area dollar-value scales, which are larger than the scales on which the other variables are measured. Some researchers have reported that, without standardization, the ADI overemphasizes those two variables. **CMS seeks comment** on

considering the ADI for purposes of determining eligibility for and the amount of any HEBA and related factors including the calculation of the ADI.

c. Reopening ACO Payment Determinations

Background. CMS reviews various statutory provisions affecting the calculation and updates of ACO benchmarks. For example, the Secretary shall:

- Estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO;
- Adjust the benchmark for beneficiary characteristics and such other factors as the Secretary determines appropriate, and updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program;
- Reset the ACO's benchmark at the start of each agreement period; and
- Be authorized to use other payment models (alternative methodologies), if doing so would improve the quality and efficiency of items and services furnished and would not increase program expenditures.

CMS cites historical examples of how it has changed MSSP based on these authorities.

The agency then reviews regulations pertaining to MSSP's reopening policy and financial calculation methodology. If CMS determines that the amount of shared savings or losses has been calculated in error, it may reopen the initial determination or a final agency determination and issue a revised initial determination (1) at any time in the case of fraud or similar fault, or (2) not later than 4 years after the notification to the ACO of the initial determination of savings or losses for the relevant performance year, for good cause.[22] After listing numerous adjustments it currently makes, CMS acknowledges it does not fully account for actions taken to protect the integrity of the Medicare program or address the impact of improper payments from fraud, etc. For instance, demanded overpayment determinations for providers resulting in adjusted claim or line item payment amounts after the 3-month claims run-out period, or aggregate amounts that are not linked to specific claims or line items, are not accounted for in Shared Savings Program expenditure calculations. Under the existing financial methodology, the agency also lacks a means to account for improper payment amounts identified in a settlement agreement between a provider/supplier and the Government or in a court's judgment.

Since January 2023, CMS has evaluated several cases where such improper payments may have impacted reconciled performance years for an MSSP ACO. Thus, CMS says it is timely and appropriate to undertake notice and comment rulemaking to establish a calculation methodology to do the following:

- Account for the impact of improper payments when reopening a payment determination;

[22] Per §425.315(a)(2), good cause may be established when (1) there is new and material evidence that was not available or known at the time of the payment determination and may result in a different conclusion, or (2) the evidence that was considered in making the payment determination clearly shows on its face that an obvious error was made at the time of payment determination. CMS has sole discretion to determine whether good cause exists for reopening a payment determination (§425.315(a)(4)).

- Describe factors that CMS may consider in exercising its discretion to reopen an ACO's payment determination under which the proposed methodology applies to recalculate the ACO's financial performance; and
- Propose to establish a process by which an ACO could request a reopening of an initial determination of shared savings or losses.

Proposed Revisions. This section describes the following proposed policies, which would generally be effective January 1, 2025:

- An addition to CMS' discretion to reopen payment determinations under §425.315(a)(4);
- Circumstances in which CMS would exercise its discretion to reopen a payment determination and issue a revised initial determination to account for the impact of identified improper payments, on which **the agency seeks comment**;
- Modifications to account for the impact of identified improper payments in recalculating expenditures and payment amounts used in MSSP financial calculations, upon reopening a payment determination;
- Adjustments to MSSP benchmark calculations to account for the impact of identified improper payments, in the event a performance year that had a revised initial determination becomes a benchmark year for an ACO, and when CMS has not yet issued an initial determination for a performance year of the ACO's current agreement period; and
- A process for ACOs to request CMS reopen a payment determination.

These are described below, along with the role of ACOs in preventing and reporting Medicare fraud.

Proposed Change to Provision Specifying CMS' Discretion to Reopen Payment Determinations. CMS proposes revisions to §425.315(a)(4) to make clear its sole discretion to determine whether or not to reopen a payment determination in the case of fraud or similar fault, as well as to determine whether good cause exists to reopen a payment determination.

Considerations for Reopening a Payment Determination to Account for Improper Payments. **CMS welcomes comment** on the considerations it describes in depth that would inform its decision of whether or not to reopen an initial determination of an ACO's financial performance pursuant to §425.315(a)(1)(i) or (ii) to account for the impact of improper payments. The following steps could ultimately lead to a reopening for MSSP ACOs:

- The CMS Center for Program Integrity (CPI) and law enforcement agencies (including the Department of Justice) *identify and quantify improper payments* that potentially impact expenditures used in program calculations not otherwise accounted for in MSSP, such as—
    - Certain demanded overpayment determinations that result in adjusted claim or line item payment amounts associated with dates of service during a performance year or benchmark year where the adjustment occurs after the 3-month claims run-out period; and
    - Improper payments resulting from conduct by individuals or entities performing functions or services related to an ACO's activities as identified in certain settlement agreements or judgments.

- CMS would perform an *initial analysis* of whether the improper payments would warrant reopening the ACO's payment determination, which may include a number of factors, such as—
    - The dollar value of improper payments and the number of claims or line items impacted; and
    - How any related impact on performance year expenditures may compare to the impact on the ACO's updated historical benchmark—in particular, whether comparing performance year expenditures to the updated benchmark expenditures used in financial reconciliation, once adjusted to account for the estimated impact of the improper payments, would result in a significant change in the amount of shared savings or losses owed by the ACO.
- CMS is considering *limits* on instances where it would reopen an initial determination to account for improper payments, to strike a balance between improving the accuracy of the calculations and ACOs' and CMS' interest in administrative finality of payment determinations; an approach of correcting even very minor errors might result in significant operational burdens for ACOs and CMS.

A variety of circumstances could lead CMS, law enforcement agencies or courts to determine whether good cause exists or whether fraud or similar fault has occurred. Difficulties then arise from the associated timelines that complicate addressing the impact of improper payments on MSSP calculations. For example, once CMS is notified of potential improper payments impacting MSSP calculations, it may take months or years to determine the actual amount of any improper payments impacting an ACO's payment determination, particularly if awaiting the conclusion of investigations and appeals.

CMS notes that its decision to reopen an initial determination for a performance year is independent of a determination to reopen it for any other performance year, including in cases where multiple performance years are impacted by the same improper payments. Thus, CMS is considering applying a combination of the following factors in determining whether to reopen an initial determination: (1) consideration of the timing of reopening and recalculating the payment determination for a performance year, and the timing of financial reconciliation for one or more performance year(s) of a subsequent agreement period that includes the affected period as a benchmark year, and (2) consideration of whether the improper payments result from conduct of individuals or entities performing functions or services related to the ACO's activities.

The agency is also considering how to differentiate between cases where improper payments originate inside the ACO[23] versus outside the ACO. For a single performance year for which CMS has issued an initial determination impacted by improper payments, it would seek to reopen the payment determination if the improper payments originated either inside the ACO or outside the ACO. However, for a performance year with a revised initial determination that becomes a benchmark year in an ACO's subsequent agreement period, CMS may consider whether to reopen each initial determination for a subsequent performance year as follows:

- In cases where improper payments originated *outside the ACO*, CMS would generally not seek to reopen payment determinations for any performance year of the ACO's

[23] That is, conduct of an ACO, ACO participant, ACO provider/supplier, ACO professional, or other individuals or entities performing functions or services related to the ACO's activities.

subsequent agreement period; however, it may consider reopening the initial determination for the performance year upon the ACO's request for a reopening if the improper payments are anticipated to result in significant adjustment to the ACO's initial determination.

- In cases where improper payments originated *inside the ACO*, CMS would reopen the payment determination for any performance year of the ACO's subsequent agreement period issued prior to the revised initial determination for the performance year corresponding to the benchmark year impacted by improper payments originating inside the ACO, if anticipated to result in a significant adjustment.

CMS seeks comment on the factors summarized above that may inform its decision of whether to reopen an initial determination of an ACO's financial performance to account for the impact of improper payments—in particular, on the approach for conducting initial analysis of whether the improper payments would warrant reopening the ACO's payment determination. The agency also seeks comment on approaches to, and considerations in connection with, balancing the need for accuracy in payment calculations with the need for administrative finality in payment determinations.

Methodology for Recalculating Expenditures to Account for Improper Payments. In a new §425.674, CMS proposes to establish the financial calculation methodology to account for the impact of improper payments on MSSP financial calculations, when reopening a payment determination pursuant to §425.315(a).

For reopening of an initial determination, the methodology would account for the impact of improper payments when (1) determining savings or losses for the relevant performance year, and (2) adjusting the benchmark by recalculating benchmark year expenditures in the event that CMS recalculates a payment determination and issues a revised initial determination for the corresponding performance year in a prior agreement period (described in greater detail below). The proposed methodology would adjust Medicare Parts A and B FFS expenditure values to account for a per capita amount of improper payments for an identified population used in calculating performance year or benchmark year expenditures, and in calculating county-level FFS expenditures used in factors based on regional expenditures.

The proposed methodology is a generalized approach, since improper payments may be associated with specific claims or line items, or may be aggregate amounts. For example, the methodology must be able to account for the denial of claims or line items that occur after the 3-month claims run out period, or in an aggregate amount, such as when error rates are extrapolated and applied to a universe of claims rather than individual claims. CMS describes other considerations and situations affecting potential recalculations (for example, the agency's decision to exclude False Claims Act settlements and damages related to an ACO's activities).

One particular scenario highlighted is if a provider's or supplier's billings for a particular HCPCS or CPT code resulted in inaccuracies in payment amounts in MSSP calculations. CMS proposes that it may address these circumstances, when reopening and recalculating the ACO's payment determination, by decreasing or entirely removing the value of HCPCS or CPT code payment amounts for certain claims or line items used in MSSP calculations. The agency

anticipates using all information available from an investigation, settlement agreement, or judgment to determine the correct payment amount or level of billing. Specifically, CMS would consider if it would be a more precise adjustment to Shared Savings Program financial calculations to adjust the claim or line item payment amounts, instead of or in addition to accounting for the amount of demanded overpayment determinations or an aggregate amount in a settlement agreement or judgment. For instance, where an investigation determined inaccurate use of a higher paying code reflected in payment amounts used in MSSP calculations, CMS may use a code with lower reimbursement that would result in a more precise adjustment to the ACO's payment determination.

CMS proceeds to walk through the detailed steps and sub-steps of the "general approach" in paragraphs (c) and (d) of the proposed §425.674 to adjust Medicare Parts A and B FFS expenditures for improper payments. Following are the highlights:

- Step 1—Identify MSSP expenditure calculation for adjustment for a performance year or benchmark year, expressed as a per capita dollar amount, to be adjusted for improper payments (§425.674(c)(1)).
- Step 2—Determine each specific population of Medicare FFS beneficiaries to calculate the expenditure amount in Step 1, expressed as person years (§425.674(c)(2)).
- Step 3—Determine per capita amount of improper payments attributable to the relevant population for the performance year or benchmark year (§425.674(c)(3)), using one or more approaches based on aggregate versus claim/line-item adjustments, etc. (§425.674(d)).
- Step 4—Subtract per capita improper payment amount from original expenditures for each of the 4 subpopulations of ESRD, disabled, aged/dual, and aged/non-dual (§425.674(c)(4)).
- Step 5—Determine adjusted regional expenditures, if applicable, for improper payments (§425.674(c)(5)) by adjusting county-level FFS expenditures determined in Step 4 for each county in the ACO's regional service area, for severity and case mix of assignable beneficiaries in the county using prospective HCC risk scores,[24] calculated separately for each of the 4 subpopulations. These would be weighted according to the ACO's proportion of assigned beneficiaries in the county consistent with existing §§425.601(d)(1), 425.603(f)(1) or 425.654(b)(1), as applicable, and aggregated.

CMS provides a hypothetical example in Table 41 (not reproduced here) for how an ACO's numbers would be recalculated, along with a description of how each specific calculation is produced using the detailed version of the steps above. Table 42 expands on the hypothetical example with calculations of the national and regional update factors using the adjusted regional and national expenditures for the performance year for each subpopulation. Table 43 shows how those results would be applied to recalculate the hypothetical ACO's financial performance to account for improper payments.

In this example, the reduction in ACO PY assigned beneficiary expenditures due to the adjustment for improper payments was larger than the reduction to the updated benchmark stemming from adjustments to PY national and regional expenditures, ultimately causing the

[24] CMS says it would not adjust the risk scores used to calculate risk adjusted county-level FFS expenditures.

hypothetical ACO to see an increase in both gross savings and shared savings. However, if accounting for improper payments results in relatively larger reductions to the expenditures for assignable beneficiaries in the ACO's regional service area or in the national assignable population, and relatively smaller reductions to the ACO's PY assigned beneficiary expenditures, the ACO might experience a reduction in shared savings or increase in shared losses, or potentially switch from earning shared savings to not earning any shared savings or to owing shared losses.

If the reopened PY becomes a BY for a subsequent agreement period (with the regulatory provisions described in the next paragraph), CMS would adjust the historical benchmark to be used for any PY in that subsequent agreement period that has not yet been reconciled. Thus, accounting for improper payments as it affects the ACO's benchmark could result in changes to the ACO's shared savings/losses for a future performance year in the opposite direction compared to the change in shared savings/shared losses observed with the initial reopening that affected PY expenditures. In the preceding hypothetical example, while the ACO earned greater shared savings for the performance year shown, it could also result in smaller shared savings (or greater shared losses) for future performance years for which that year becomes a benchmark year (because the adjustment for improper payments in the benchmark year causes a reduction in the overall benchmark with no corresponding reduction to ACO PY expenditures).

Adjusting Historical Benchmarks to Account for the Impact of Improper Payments. During the term of the ACO's agreement period, CMS adjusts an ACO's historical benchmark annually to account for certain changes, as specified in MSSP regulations.[25] For additional specificity, CMS proposes to adjust an ACO's historical benchmark in reaching an initial determination of financial performance for a performance year. The same methodology would be applied to recalculate the ACO's BY expenditures as used in recalculating the expenditures for the performance year, which would improve the accuracy of the BY calculations used in reaching an initial determination for a PY, by addressing the impact of previously identified improper payments on the expenditure calculations.

As an example, assume CMS issues a revised initial determination for PY 2022 in December 2025, for an ACO that renewed to continue its participation under a new agreement period beginning on January 1, 2025. The proposed policy would enable CMS to use the same methodology for calculating BY 2022 expenditures for PY 2025 in reaching the initial determination for PY 2025.

Specifically, CMS proposes to amend §§425.601(a)(9) and 425.652(a)(9) to specify this adjustment to the historical benchmark. For the second and each subsequent performance year during the term of the agreement period, the ACO's benchmark would be adjusted for changes in values used in benchmark calculations as a result of issuance of a revised initial determination. The agency would also recalculate benchmark year expenditures to account for the impact of improper payments, for the benchmark year corresponding to a performance year for which CMS issued a revised initial determination. In recalculating expenditures for the benchmark year, CMS would apply the same calculation methodology applied in recalculating expenditures for the

[25] At §425.601(a)(9) for the "related adjustment" for agreement periods beginning on or after July 1, 2019, and before January 1, 2024; at §425.652(a)(9) for agreement periods beginning on or after January 1, 2024.

corresponding performance year, in accordance with the proposed new section of the regulation at §425.674.

ACO Reopening Requests. At §425.315(b), CMS proposes a process through which an ACO may request a reopening of an initial or final agency determination of shared savings/losses. Although an ACO's submission of a reopening request is optional, the agency proposes to require that the request be in a form and manner specified by CMS and that the timing of the ACO's reopening request be consistent with the timeframes specified in existing §425.315(a)(1)(i) and (ii).[26]

To evaluate an ACO's reopening request, CMS says it will need to receive sufficient, detailed information from ACOs, including the following:

- ACO identifier(s) (also referred to as "ACO ID") and Legal Business Name(s).
- Identity of the provider or supplier for which there may be improper payment(s), or that may be suspected of fraud or similar fault, including name, NPI or Provider Transaction Access Number (PTAN), TIN, or other identifier.
- Time period during which potentially impacted claims were submitted or improper conduct occurred.
- Short description of the improper payment, alleged fraud or similar fault, and how it was identified, including information such as any specific claim type codes and HCPCS or CPT codes.
- Evidence of financial impact on the ACO's shared savings/losses calculation, such as any analysis supporting the calculation of financial impact to the ACO and a list of beneficiaries assigned to the ACO for whom claims were submitted by the provider or supplier suspected of fraud or similar fault, or for which expenditures may be impacted by improper payments.

As previously mentioned, since a recalculation of shared savings/losses to account for improper payments could result in a variety of outcomes, an ACO should weigh these potential outcomes when considering whether to submit a reopening request.

Since the proposed process for requesting a reopening, whether for good cause or for fraud or similar fault, would be a new process, **CMS seeks comments and suggestions** on the form and manner in which CMS should receive these requests, as well as on approaches to ensuring that ACOs submit reopening requests with sufficient information to allow CMS to identify and evaluate the impact on financial performance.

The following steps illustrate how CMS may review an ACO's request to reopen a payment determination to account for the impact of improper payments:

- Upon receiving the request, CMS would evaluate it and ask for supplemental information if needed.
- CMS would work with CPI and law enforcement agencies to identify, validate and quantify improper payments potentially impacting expenditures used in program

[26] That is, either (i) at any time in the case of fraud or similar fault, or (ii) not later than 4 years after the date of the notification to the ACO of the initial determination of savings or losses for the relevant performance year for good cause.

calculations, potentially contingent on the conclusion of an investigation that is underway.

- CMS may conduct initial analysis to consider the basis for a reopening and the significance of the improper payments to an ACO's financial calculations, as previously described.
    - If CMS finds the potential improper payments do not meet CMS' standards for reopening the payment determination, it anticipates notifying the ACO of that decision.
    - If CMS decides to reopen the ACO's payment determination for a performance year, it would do the following:
        - Recalculate expenditures and the ACO's shared savings/losses (as described above), issue a revised initial determination, and engage in payment activities and recoupment activities, as needed.
        - During the recalculation period, identify whether the relevant performance year is also serving as a benchmark year for the ACO's current agreement period and prepare to adjust the ACO's benchmark year accordingly.

If the identified improper payments have the potential to impact other ACOs, CMS anticipates determining whether to reopen the payment determination for *only* the ACO that submitted the reopening request. However, CMS *may* initiate analysis of the impact of improper payments on Shared Savings Program financial calculations and potentially reopen the payment determination for other ACOs absent their request. For example, CMS anticipates initiating analysis of the impact of improper payments on an ACO's payment determination upon learning of improper payments originating inside the ACO that may potentially impact MSSP calculations, and may reopen the ACO's payment determination to address program integrity concerns.

Because investigations into improper payments may involve varying degrees of complexity and scale, CMS may not always be able to conduct a reopening within a specific timeframe after an ACO submits a reopening request. As previously mentioned, the process for analyzing an ACO's reopening request, reaching a decision on whether to reopen the initial determination, recalculating the ACO's payment determination, and issuing a revised initial determination may occur over a period of months or potentially years; it may also have impacts on future agreement periods. In fact, when CMS and law enforcement officials have investigations underway, CMS must refrain from providing details to ACOs and others of pending actions, in order to protect the integrity of those investigations. Thus, the agency may be limited in the information it can communicate to an ACO about its consideration of the reopening request.

Preventing and Reporting Medicare Fraud. CMS observes that ACOs can help prevent fraud and abuse within the Medicare program or in other federal health care programs. Current regulations (§425.300) require ACOs to have a compliance plan that must include, among other things, a method for employees or contractors of the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to anonymously report suspected problems related to the ACO to the compliance officer (§425.300(a)(3)). ACOs must also report probable violations of law to an appropriate law enforcement agency (§425.300(a)(5)). CMS then lists multiple ways for ACOs to report potential fraud or abuse.

CMS notes that reporting of potential fraud or abuse does not itself constitute a reopening request.

d. Mitigating the Impact of Significant, Anomalous, and Highly Suspect Billing Activity on Shared Savings Program Financial Calculations in 2024 or Subsequent Years

Background. CMS reviews a variety of statutory provisions, highlighting the flexibility it has to adjust ACO benchmarks and, with that flexibility, some of the modifications it has made over the years.

Recently, ACOs and other interested parties have raised concerns about an increase in billing to Medicare for selected intermittent urinary catheter supplies on Durable Medical Equipment, Prosthetics, Orthotics & Supplies (DMEPOS) claims in 2023, alleging that the increase in payments represents fraudulent activity (which CMS calls the "alleged conduct"). This represents significant, anomalous, and highly suspect (SAHS) billing activity. Generally, a level of billing for a given HCPCS or CPT code is considered SAHS billing activity when a given HCPCS or CPT code exhibits a level of billing that represents a significant claims increase—either in the volume or dollars with national or regional impact (that is, not impacting only one or few ACOs)—and a deviation from historical utilization trends that is unexpected and not clearly attributable to reasonably explained changes in policy or the supply or demand for covered items or services. It would cause significantly inaccurate and inequitable payments and repayment obligations in the Shared Savings Program if not addressed.

Current MSSP regulations do not provide a basis for CMS to adjust program expenditure or revenue calculations to remove the impact of SAHS billing activity. As previously discussed, CMS may reopen an initial determination or a final agency determination and issue a revised initial determination at any time in the case of fraud or similar fault, and not later than 4 years after the date of the notification to the ACO of the initial determination of savings/losses for the relevant performance year for good cause (§425.315). However, this does not allow for CMS to address SAHS billing activity, which must be addressed prior to conducting financial reconciliation (initial determination), to prevent significant inequity and inaccurate payment determinations.

CMS lists numerous MSSP calculations and payments that could be affected by SAHS billing activity, such as:

- The historical benchmarks for an ACO;
- Future financial reconciliation performed against those benchmarks—that is, shared savings/losses calculations; and
- An ACO's revenue status and the amount of funds an ACO in a two-sided model must secure as a repayment mechanism, due to inaccurate revenue and expenditure calculations.

Failing to address SAHS billing activity would jeopardize the integrity of the Shared Savings Program, affecting the 480 ACOs in the Shared Savings Program with over 608,000 health care providers who care for 10.8 million assigned FFS beneficiaries. CMS says holding an ACO

accountable for substantial losses due to SAHS billing activity is not only inequitable but will dramatically increase the level of risk associated with participation, making the Shared Savings Program unattractive.

In a separate proposed rule entitled "Medicare Program: Mitigating the Impact of Significant, Anomalous, and Highly Suspect Billing Activity on Medicare Shared Savings Program Financial Calculations in Calendar Year 2023" (89 FR 55168, July 3, 2024—hereafter referred to as the SAHS billing activity proposed rule), CMS proposed an approach to address the SAHS billing activity identified for 2023. That rule would exclude payment amounts for two HCPCS codes[27] on DMEPOS claims submitted by any supplier from expenditure and revenue calculations used for the following:

- Assessing PY 2023 financial performance of Shared Savings Program ACOs;
- Establishing benchmarks for ACOs starting agreement periods in 2024, 2025, and 2026; and
- Calculating factors used to determine revenue status and repayment mechanism amounts in the application and change request cycle for ACOs applying to enter a new agreement period beginning on January 1, 2025, or continue their participation in the program in PY 2025, respectively.

There will be a 30-day public comment period on the SAHS billing activity proposed rule (comments due July 29, 2024) so as to minimize the negative impact on ACOs of a delay in the issuance of PY 2023 initial financial determinations and disbursement of performance payments, as well as to other program milestones, necessitated by the calculation of amounts under the financial methodology proposed in the SAHS billing activity proposed rule.

Proposed Revisions. In a new §425.672, CMS is proposing to establish a policy that would allow it to proactively make similar adjustments beginning with 2024, should new SAHS billing activity be identified. It anticipates this will be a rare occurrence, as evidenced by the SAHS billing activity surrounding these catheter codes in 2023 being the first occasion in the program's 12-year history to consider this issue. CMS would notify ACOs and ACO applicants of its determinations to remove any codes and the associated aggregate per capita dollar amount as part of the annual financial reconciliation process. Such a policy would do the following:

- Allow CMS to move quickly to make adjustments to financial calculations without having to engage in additional rulemaking, ensuring timely issuance of initial determinations of savings/losses and disbursement of earned performance payments;
- Provide ACOs with greater certainty that they will not be held accountable for SAHS billing activity that is out of their control; and
- Limit requests to reopen initial determinations, thus reducing burden for ACOs and CMS.

Identifying SAHS Billing Activity. In proposed §425.672(b), CMS would have the sole discretion to identify cases of SAHS billing activity for a particular year warranting adjustment of MSSP financial calculations. CMS says it would seek to identify and monitor any codes that would potentially trigger the adjustment policy by meeting the high bar for removal under the criteria

[27] A4352 (*Intermittent urinary catheter; Coude (curved) tip, with or without coating (Teflon, silicone, silicone elastomeric, or hydrophilic, etc.)*, each) and A4353 (*Intermittent urinary catheter, with insertion supplies).*

used to determine SAHS billing activity. Shortly after the start of a calendar year, CMS would make a final determination as to which codes, if any, warrant adjustments for the previous calendar year. For example, in early 2026, CMS would make a final determination of whether any codes met the high bar for removal under the criteria used to determine SAHS billing activity in 2025.

CMS lists multiple criteria (not listed in the proposed regulatory language) that it would consider in determining whether SAHS billing activity warrants removal from MSSP financial calculations:

- The observed increase in claims for a HCPCS or CPT code year-to-year meets the definition of SAHS billing activity, which CMS says defined elsewhere in this section of this proposed rule;[28]
- The observed billing activity has national or regional impact or significance;
- If no action is taken, there would be an imbalance between ACO performance year and historical benchmark year expenditures;
- Use of payment amounts associated with the SAHS billing activity could result in payment inaccuracies that produce significantly inaccurate and inequitable payment determinations due to factors beyond the control of ACOs; and
- The claims in question may be disproportionately represented by Medicare providers or suppliers whose Medicare enrollment status has been revoked.

CMS elaborates on each in the preamble.

Adjustments to Shared Savings Program Calculations. In proposed §425.672(c), in the event that CMS identifies one or more HCPCS or CPT codes with SAHS billing activity in 2024 or after that warrant adjustment, it would exclude all Medicare Parts A and B payment amounts associated with the identified codes on specified claim types submitted by any provider or supplier from expenditure and revenue calculations for the relevant calendar year. For example, if CMS identifies one or more codes with SAHS billing activity in 2025 that warrant adjustment, it would exclude payments for those codes for calculations where 2025 is the performance year and in calculations where 2025 is a benchmark year for ACOs.

It would also adjust the 3 most recent years prior to the start of the ACO's agreement period used in establishing the historical benchmark used to reconcile the ACO for a performance year corresponding to the calendar year for which the SAHS billing activity was identified (proposed §425.672(d)(2)). In the example where CMS identified SAHS billing activity for 2025, benchmark expenditures (ACO, national, and regional) would be adjusted for 2019, 2020, and 2021 for an ACO that began an agreement period in 2022 (for which PY 2025 is the fourth performance year in its agreement period) and would adjust benchmark expenditures (ACO, national, and regional) for 2022, 2023, and 2024 for an ACO that began its agreement period in 2025 (for which PY 2025 is the first performance year in its agreement period).[29] This would achieve greater consistency between the benchmark period and the performance year, given the exclusion of all payments on specified claim types for the selected codes from performance year

[28] HPA did not find it.

[29] Note that in computing benchmark expenditures for 2023 in this example, because 2023 is a benchmark year, CMS would also exclude payments for the catheter claims with SAHS billing activity in 2023, as proposed in the SAHS billing activity proposed rule, if finalized.

calculations, including payments that would have been made in the absence of any SAHS billing activity.

Specifically, in proposed §425.672(c), CMS lists numerous MSSP calculations for which, as applicable, it would exclude all Medicare Parts A and B payment amounts associated with a HCPCS or CPT code on claims for the specified claim types displaying SAHS billing activity, including the following:

- Medicare Parts A and B FFS expenditures for an ACO's assigned beneficiaries for all purposes including establishing, adjusting, updating, and resetting the ACO's historical benchmark and determining performance year expenditures.
- Medicare Parts A and B FFS expenditures for assignable beneficiaries as used in determining county-level FFS expenditures and national Medicare FFS expenditures.
- Medicare Parts A and B FFS revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track.
- Total Medicare Parts A and B FFS revenue of ACO participants and total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries (for purposes such as determinations of loss sharing limits in the two-sided models of the BASIC track, eligibility for AIP, and expanded criteria for certain low revenue ACOs participating in the BASIC track to qualify for shared savings in the event the ACO does not meet the minimum savings rate).
- Calculation or recalculation of the amount of the ACO's repayment mechanism arrangement according to §425.204(f)(4).

CMS notes the listed calculations are the same that CMS adjusts for a beneficiary's episode of care for treatment of COVID-19, specified at §425.611(c), with a few exceptions.

The changes in this section would apply to ACOs currently participating in PY 2024 and thus would constitute retroactive rulemaking. Section 1871(e)(1)(A)(ii) of the Act permits a substantive change in regulations, etc., to be applied retroactively if the failure to do so would be contrary to the public interest. CMS says failing to apply the proposed changes retroactively to PY 2024 would be contrary to the public interest because it would unfairly punish Shared Savings Program ACOs by forcing them to unexpectedly assume a substantial magnitude of financial risk for costs outside of their control and not previously contemplated in the program, undermining both the program's sustainability and the public's faith in CMS as a fair partner.[30] **CMS seeks comment** on the proposal to apply the policy retroactively to PY 2024, including whether failing to apply the policy retroactively would be contrary to the public interest and how it would affect ACOs and their ability to participate in the Shared Savings Program.

e. Seeking Comment on Establishing Higher Risk and Potential Reward under the ENHANCED Track

Background. CMS has been considering a higher risk Shared Savings Program track under which the shared savings/loss rate would be somewhere between 80 percent and 100 percent—that is, higher than in the ENHANCED track—and builds on the experience of the Next Generation

[30] That is, in the event that CMS determines SAHS billing activity impacts 2024.

ACO (NGACO) and ACO REACH Models. A higher risk track would offer ACOs increased incentives to generate savings, as they would receive a greater share of any gross savings, thus helping improve care delivery by promoting innovations in the delivery of high-quality care that is more patient-centered.[31]

In the 2024 PFS final rule, CMS summarized public comments received in response to its RFI regarding a potential track with higher risk than the current ENHANCED track (88 FR 79225-79227). Commenters were broadly supportive and referenced existing policies under ACO REACH and the NGACO Model, suggesting that such a track would serve to encourage more participation in the Shared Savings Program and help ACOs deliver more person-centered care to beneficiaries in Traditional Medicare. These features included prospective payments, full sharing rates (a sharing rate of 100 percent, similar to the Global Risk Sharing Option in the ACO REACH Model) as well as a benchmark discount rate (a reduction of the benchmark by a predetermined percentage) to protect the Medicare Trust Funds.

CMS seeks comment on a participation option that would allow for higher risk and reward than currently available under the ENHANCED track, replacing the existing ENHANCED track in order to avoid the self-selection issues that would occur if a higher risk track were to be included alongside the ENHANCED track. If both were available, CMS is concerned that only the highest-performing ACOs would self-select into the higher of the two risk tracks. While the RFI in the 2024 PFS rulemaking was on this topic, CMS is concerned that ACOs did not have enough detailed information to appropriately weigh the tradeoffs associated between a higher risk/reward option and the current ENHANCED track; the additional information will allow ACOs and other interested parties to provide more forthright and helpful feedback.

Before laying out considerations for incorporating potential higher risk/reward under the ENHANCED track, CMS provides additional background for both the current ENHANCED track and other Innovation Center models. Some highlights:

- The current ENHANCED track—
    - It is a two-sided model with the highest level of risk and potential reward in MSSP.
    - To qualify for shared savings payments, an ACO must meet (1) a minimum savings rate (MSR), (2) the quality performance standard or alternative quality performance standard established under §425.512, and (3) MSSP eligibility requirements.
        - For ACOs meeting the applicable quality performance standard, the final shared savings rate is 75 percent (the maximum)—or savings at a rate of 75 percent multiplied by the ACO's health equity adjusted quality performance score, if the ACO meets the alternative quality performance standard at §425.512(a)(5)(ii).

[31] A CBO report from April 2024, "Medicare Accountable Care Organizations: Past Performance and Future Directions," stated that higher sharing rates might incentivize providers to decrease spending, as they would stand to gain a larger portion of the savings generated. While this might diminish CMS savings in the short term, the report suggests this would increase participation in MSSP and provide a means for CMS to manage long-term healthcare spending growth. CBO notes, however, the necessity of striking a delicate balance between designing financial incentives to encourage ACOs' active participation in MSSP versus ensuring that such participation leads to savings for Medicare.

        - The payment is subject to a cap of 20 percent of the updated benchmark.
    - When requiring payment of shared losses, the ACO's share of losses is determined using a sliding scale based on its health equity adjusted quality performance score (if the applicable quality performance standard or alternative quality performance standard is met), with a minimum shared loss rate of 40 percent and maximum of 75 percent.
        - If the ACO fails to meet the quality performance standard, it is subject to 1st dollar losses at a rate of 75 percent.
        - Shared losses are subject to a cap of 15 percent of the updated benchmark.
    - The ACO's historical benchmark expenditures are adjusted by Medicare enrollment type by a specified percentage of the difference between the average per capita expenditure amount for the ACO's regional service area and the ACO's historical benchmark amount (§425.652(a)(8), referred as the "regional adjustment"), as described in detail in the preamble, with varying percentages that apply.[32]
    - In terms of enrollment as of January 1, 2024—
        - 43 percent (207 of 480) MSSP ACOs are in the ENHANCED track.
        - Among ACOs in the ENHANCED track, 61 percent have selected an MSR/MLR of 0.5 percent or greater, while 39 percent have selected an MSR/MLR of 0.0 percent.
- NGACO Model—
    - NGACOs were offered the choice between two risk arrangements.
        - Under the *partial risk arrangement*, the NGACO could receive or owe up to 80 percent of savings/losses.
        - Under the *full risk arrangement*, the NGACO could receive or owe up to 100 percent of savings/losses.
        - NGACOs choose a cap on gross savings/losses, expressed as a percentage of the benchmark, ranging from 5 percent to 15 percent.
    - In PYs 1-3, a discount was applied to the NGACO's benchmark (3 percent, with various adjustments, that allowed the final discount to vary from 0.5 percent to 4.5 percent).
    - In PYs 4-6, a discount of 0.5 percent was applied to the benchmark under the partial risk arrangement, and a discount of 1.25 was applied to the benchmark under the full risk arrangement, to ensure savings to Medicare.
    - ACOs that elected a risk cap greater than 5 percent and participated in model population-based payment mechanisms achieved greater declines in spending.
    - While the NGACO Model reduced spending in Medicare Parts A and B, CMS paid back these reductions in the form of shared savings payments to ACOs, highlighting the need to balance the tradeoff between incentivizing participation in higher levels of risk/reward and reducing the risk of loss to Medicare.
- ACO REACH Model—

[32] Among ACOs participating in PY 2024, 78 percent of BASIC track ACOs (176 of 227) received a positive regional adjustment versus 95 percent (155 of 163) of ACOs in the ENHANCED track. A positive regional adjustment indicates that the ACO's expenditures were less than that of their regional service area. For ACOs receiving a positive regional adjustment, the average regional adjustment amount was 2.21 percent ($237) of historical benchmark expenditures.

- REACH ACOs are offered the choice of participating under the Global or the Professional Risk Sharing Options.
  - Global Risk Sharing Option:
    - ACOs retain up to 100 percent of the savings/losses on all savings up to 25 percent of their benchmark, with reduced sharing rates for savings exceeding 25 percent of their benchmark.
    - However, to ensure savings are also generated for CMS, a discount is applied to the benchmark, which varies by performance year—2 percent for PYs 2021 and 2022, 3 percent for PYs 2023 and 2024, and above 3.5 percent for PYs 2025 and 2026.
  - Professional Risk Sharing Option:
    - No discount applies.
    - ACOs are only eligible to retain 50 percent of savings or owe 50 percent of any losses.
  - Preliminary evaluation results of the first 2 performance years of the Global and Professional Direct Contracting Model, before its transition to the ACO REACH Model, suggest that participating ACOs had mixed results in gross spending but consistent, significant increases in net spending.
    - Standard ACOs, comprised of organizations that generally have experience serving Medicare FFS beneficiaries, increased gross spending, concentrated among the integrated delivery system/hospital system ACOs.
    - High Needs ACOs that serve Medicare FFS beneficiaries with complex needs, including dually eligible beneficiaries, decreased gross spending.

Considerations for Incorporating Higher Risk and Potential Reward Under the ENHANCED Track. A revised ENHANCED track could be implemented if, per section 1899(i)(3) of the Act, the Secretary determines that it would enhance the quality and efficiency of items and services furnished and does not result in program expenditures greater than those that would result under the statutory payment model. CMS says that increasing the sharing rate in the ENHANCED track may need to be accompanied by other modifications to ensure compliance with section 1899(i)(3).

CMS is concerned about selective participation—that is, which ACOs would choose to participate in a higher risk track. For example, ACOs with a history of high levels of earned shared savings may be more likely than others to switch to the higher risk track so they can receive additional benefit from the higher levels of potential reward offered in a higher risk track, potentially jeopardizing 1899(i)(3) compliance. Thus, if a higher risk track were to be offered, CMS would consider replacing the existing ENHANCED track in order to prevent further selective participation.

CMS is seeking comment on the following potential features of a revised ENHANCED track:

- Benchmark Discount Rate

- What discount rate would be appropriate to protect Medicare Trust Funds while providing an adequate incentive for ACOs to participate in a potential revised ENHANCED track?
- What level of discount would be acceptable to ACOs participating in the Shared Savings Program, and what would be considered too high?
- Might the model features described below replace a discount to the benchmark, while balancing financial incentives for ACOs and risk to CMS?

- Tapered Sharing Arrangements
  - Although ACOs in the ENHANCED track can receive a shared savings payment of up to 20 percent of their updated benchmark (once the MSR is met or exceeded) or be liable for losses not to exceed 15 percent of their updated benchmark (once the MLR is met or exceeded), CMS could set up marginal savings bands or risk corridors under which shared savings or losses rates would vary with the amount of gross savings or losses. That is, as gross savings/losses increase, the ACO will retain a progressively smaller portion of the total savings or will be responsible for a progressively smaller portion of the total losses, with an example shown in Table 44, reproduced below.

TABLE 44: Hypothetical Marginal Shared Savings Bands

Gross savings as % of benchmark	Shared Savings/Loss Rate[1]
0-10%	100%
10-15%	60%
15-20%	40%
>20%	0%
Losses	50%-100%[2]

[1] Percentage of savings or losses retained by the ACO.
[2] Shared Loss Rate would depend on an ACO's quality performance, similar to §425.610(f)(4).

  - **CMS seeks comment** on whether the hypothetical marginal shared savings bands shown above are—
    - Appropriate to provide sufficient incentive for an ACO to participate in a potential revised ENHANCED track,
    - Whether the tapering schedule should begin with lower shared savings rates and feature increasing rates as an ACO generates greater amounts of savings,
    - Whether a potential tapering schedule should be symmetrical with respect to shared loss rates, and
    - Whether marginal shared savings bands provide the right incentives to ACOs relative to the fixed savings rate in the current ENHANCED track.

- MSR/MLR
  - CMS is considering a symmetric MSR/MLR of 0 percent. This would increase many ACOs' exposure to both positive savings and negative risk, guaranteeing that:
    - Any ACO generating savings would share in those savings, and

        - ACOs with performance year expenditures greater than their historical benchmark would be liable for those losses.
    - **CMS is seeking comment** on whether a potential revised ENHANCED track should retain the existing symmetric MSR/MLR selection options that currently exist for ACOs in a two-sided risk model under §425.610(b)(1).
- Cap on Regional Adjustment Weight
    - CMS is seeking comment on adjusting the weights used to calculate the regional adjustment amounts under §425.656(e) for ACOs in the revised ENHANCED track, which may take the form of applying a cap of 35 percent to all the weights used to calculate regional adjustment amounts (which would impact any ACOs in a second or subsequent agreement period subject to a regional adjustment if their historical benchmark spending is lower than their regional service area).
    - Overall, this feature would reduce the cost to CMS associated with high regional adjustments by reducing an ACO's historical benchmark in the event that an ACO in a second or subsequent agreement period receives a large positive regional adjustment, which may decrease the need for higher benchmark discount rates or lower tapered shared savings rates that are less favorable to ACOs and limit incentives for ACOs to transition from the BASIC track to the revised ENHANCED track.
    - **CMS seeks comment** on whether further reductions to or the removal of the regional adjustment to the historical benchmark would be appropriate as part of a potential revised ENHANCED track, and whether maintaining the regional adjustment in its current state would warrant further changes to the revised ENHANCED track features described above, including a discount to the benchmark or lower tapered shared savings rates.
- Payment Mechanisms. **CMS is seeking comments** on alternative payment mechanisms that the Innovation Center has tested and their ability to help transform care delivery and improve health outcomes for MSSP ACOs. These mechanisms test whether alternative payment flows (that is, those other than FFS reimbursement) facilitate better investment in infrastructure and care coordination and encourage innovative downstream payment arrangements that can improve health outcomes. The alternative payment mechanisms on which CMS seek comments are the following:
    - Infrastructure Payments—CMS makes a payment to the ACO (in addition to FFS reimbursement to the participating providers and suppliers) that is unrelated to claims, distributed either as a lump sum or per beneficiary per month payment, and recouped during payment reconciliation.
    - Population-Based Payment, All-Inclusive Population-Based Payment, or Advance Payment Option—CMS provides a percentage of FFS reimbursement to the ACO in the form of a monthly payment to support ongoing ACO activities and provide the ACO flexibility in the types of arrangements it enters into with provider/suppliers. The ACO and providers with whom it has a written business arrangement determine percentage reductions to the base FFS payments to the providers interested in this payment arrangement, ranging from 1-100 percent. CMS pays the projected total annual amount taken out of the base FFS rates to the ACO in monthly payments; at the end of each performance year, the amount of payment paid to ACOs participating in this type of payment option is reconciled

against the reductions actually made to claims payments to providers participating in these arrangements.

- Capitation. CMS describes the two capitation payment options in ACO REACH—Primary Care Capitation and Total Care Capitation—and provides a link to more details at https://www.cms.gov/files/document/aco-reach-py24-financial-ops-capitation-and-payment-mechanisms.pdf.

The agency then lists **the following 11 specific questions for feedback** related to implementation of a revised ENHANCED track with higher risk and potential reward, as well as comments that could inform changes to the Shared Savings Program and future Innovation Center ACO models:

1. What would the option of a revised ENHANCED track allow an ACO to do that they are unable to do currently?
2. How would higher downside risk impact an ACO's care delivery strategies, including advanced primary care, behavioral health, specialty integration, and integration with community-based organizations to improve health outcomes or advance health equity?
3. How does higher downside risk impact an ACO's downstream provider arrangements to further advance incentives to reduce delivery of low value services and the total cost of care, and to increase savings performance?
4. What types of organizations, including ACOs and providers, are interested in a higher risk and reward option in the Shared Savings Program?
5. What additional flexibilities or features (for example, benefit enhancements, advance payments, capitation payments, etc.) would ACOs in a revised ENHANCED track with higher risk and potential reward want CMS to offer to help them be successful in improving the quality of care and reducing costs?
6. How should a revised ENHANCED track with higher risk and potential reward also require additional accountability for quality? Should ACOs in this revised track be required to report all payer/all patient quality measures?
7. Should a revised ENHANCED track require ACOs with earned shared savings to share savings with beneficiaries or spend a flat dollar amount or a certain percentage on beneficiaries in the form of items or services not covered by original Medicare (for example, meals, dental, vision, hearing, or Part B cost-sharing reductions)?
8. How should CMS consider the discount, sharing rate, and risk corridors or marginal savings bands in the design of a higher risk option that can realize savings for Medicare? Are there special considerations that CMS should bear in mind for different types of ACOs (for example, low revenue, high revenue, health system-based, safety net, etc.)?
9. How might CMS improve beneficiary assignment and are there different considerations for different types of ACOs (for example, low revenue, high revenue, health system-based, safety net)?
10. What other features should CMS consider in designing financial benchmarks that balance prospectivity and accuracy, and that can lead to savings for both ACOs and Medicare? How might administratively set benchmarks achieve these goals and what considerations should CMS bear in mind if testing administrative benchmarking?
11. What other ways are there to increase participation by healthcare providers and suppliers in the Shared Savings Program and future Innovation Center ACO models,

including how an ACO model requiring provider participation or stronger participation incentives might be designed?

f. Proposed Technical Change for Consistency in Financial Calculations

Background. For MSSP ACOs, prospective hierarchical condition category (HCC) risk score growth is capped between BY3 and the performance year (§§425.605(a)(1) and 425.610(a)(2)). For agreement periods beginning on or after January 1, 2024, positive adjustments in prospective HCC risk scores are subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year (positive or negative) plus 3 percentage points. The cap applies to prospective HCC risk score growth for any Medicare enrollment type (e.g., ESRD) only if the ACO's *aggregate* growth in prospective HCC risk scores between BY3 and the performance year across *all* of the Medicare enrollment type exceeds this cap. The aggregate growth is calculated by taking a weighted average of the risk ratio for demographic risk scores or prospective HCC risk scores, as applicable, for each Medicare enrollment type using specified weights.

The current regulations further describe how CMS caps prospective HCC risk score growth in the ACO's regional service area (§425.655), based on aggregate growth in regional prospective HCC and demographic risk scores between BY3 and the performance year for each Medicare enrollment type. The agency then calculates aggregate risk score growth by taking a weighted average of the regional prospective HCC or demographic risk ratios, as applicable, across the four Medicare enrollment types, using specified weights. It then determines the cap on regional risk score growth (§425.655(e)), if the ACO's regional risk score growth is subject to a cap and, if so, applies a regional risk score growth cap adjustment factor for each Medicare enrollment type, as applicable (§425.655(f)).

In describing this in the 2024 PFS final rule, CMS included a footnote (88 FR 79178) that indicated that the weights to be used to compute aggregate risk score growth for this calculation are the same as the weights to be used when calculating weighted average ACO prospective HCC and demographic risk ratios under the risk adjustment methodology for capping ACO risk score growth codified in §§425.605(a)(1)(ii)(C) and 425.610(a)(2)(ii)(C). Again, the intent was to use the same weights in both the regional risk score growth cap calculation and the ACO risk score growth cap calculation.

However, in codifying the methodology for the regional risk score growth cap in §425.655, CMS inadvertently introduced a discrepancy. In §425.655(d)(2), where CMS codified how it would calculate aggregate risk score growth used in determining the cap to apply to regional prospective HCC risks score growth, it described the weight applied to the growth in demographic or prospective HCC risk scores for each Medicare enrollment type as equal to the product of the ACO's *regionally adjusted historical benchmark expenditures* for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type, rather than the *historical benchmark expenditures* for that enrollment type and the performance year person years for that enrollment type.

In other words, while §§425.605(a)(1)(ii)(C) and 425.610(a)(2)(ii)(C) say that CMS will use the ACO's historical benchmark expenditures in calculating the weights used to cap ACO risk score growth, §425.655(d)(2) says CMS will use an ACO's regionally adjusted historical expenditures in calculating the weights used in the calculation of regional risk score growth cap. Thus, the regulatory language is inconsistent, even though CMS had indicated in the 2024 PFS final rule that it would use the same weights in both calculations. Furthermore, CMS elaborates on how it is unclear how it would apply in practice the calculation as currently described at §425.655(d)(2).

Proposed Revisions. To align with the intent described in the footnote in the 2024 PFS final rule (88 FR 79178) to use the same weights to calculate the cap for prospective HCC risk score growth in an ACO's regional service area as the weights used to calculate the cap on prospective HCC risk score growth for the ACO, CMS is proposing technical changes to the regulation text at §§425.605(a)(1)(ii)(C), 425.610(a)(2)(ii)(C), and 425.655(d)(2). The same proposed language will be used across the three provisions and clarify that the weight applied to the growth in ACO and regional risk scores for each Medicare enrollment type, respectively, would be equal to the product of the ACO's historical benchmark expenditures, adjusted in accordance with §425.652(a)(8), for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type. The revised language will also clarify the interaction with other policies proposed in this rule (for example, the health equity benchmark adjustment).

The technical changes proposed here relate to benchmark calculations for ACOs in agreement periods beginning on or after January 1, 2024 and thus would constitute retroactive rulemaking. CMS restates the statutory conditions for implementing retroactive rulemaking, which it says apply here. Specifically:

- The proposed technical change would align the regulation text with its stated intention described in previous rulemaking.
- The current regulation text fails to provide sufficient clarity with regard to how CMS will calculate the weights used to calculate aggregate ACO or regional risk score growth.
- Failure to apply the proposed changes retroactively would be contrary to the public interest because it creates unintended ambiguity in the standard CMS will use when calculating risk score growth.

8. Beneficiary Notification Requirements

a. Proposal to Modify Requirements for When ACOs Must Provide the Beneficiary Information Follow-Up Communication

ACOs are required to notify beneficiaries about (i) the ACO's participation in the MSSP, (ii) the beneficiary's option to decline claims data sharing; and (iii) the beneficiary's ability to select a provider for purposes of voluntary alignment.[33] In addition, ACOs are required to provide an additional follow-up notification with a beneficiary who has received that standardized beneficiary written notification (known as the beneficiary information follow-up communication). The follow-up communication is intended to provide the chance for the beneficiary and provider to discuss coordination of care, benefits of receiving care from an ACO

[33] See §425.312(a).

provider, organizational operations of the ACO, and how data is used to improve care and report quality outcomes.[34] The ACO must provide the follow-up communication no later than the earlier of the beneficiary's next primary care service or 180 days from the date of the standardized notification, and must document the follow-up communication in a record system supported by the ACO and make the information available to CMS upon request.

In response to concerns raised by ACOs about difficulty in operationalizing the timing requirement of the follow-up communication, CMS proposes, effective January 1, 2025, to simplify the requirement by requiring it occur not later than 180 days from the date the standardized notice was provided.

b. Limit the Distribution of the Beneficiary Notification to Beneficiaries Likely to be Assigned for ACOs under Preliminary Prospective Assignment with Retrospective Reconciliation

ACOs that select preliminary prospective assignment with retrospective reconciliation[35] are currently required to provide the standardized written beneficiary notice to *all* FFS beneficiaries before or at "the first primary care service visit during the first performance year in which the beneficiary receives a primary care service from an ACO participant."[36] There are a number of reasons why this results in ACOs being required to send these notices to FFS beneficiaries who are not eligible to be assigned to the ACOs.

Therefore, CMS proposes, effective January 1, 2025, to modify the notice distribution requirement for ACOs that select preliminary prospective assignment with retrospective reconciliation by more precisely specifying the FFS beneficiaries to whom the notice must be provided. These ACOs would be required to provide the notice at least once during an agreement period to each beneficiary who received at least one primary care service during the assignment window or applicable expanded window for assignment from (1) a physician who is (i) an ACO professional in the ACO and (ii) is a primary care physician or has one of the primary specialty designations included in §425.402(c), (2) a FQHC or RHC that is part of the ACO, or (3) an ACO professional in the ACO who is designated by the beneficiary as responsible for their overall care coordination. ACOs that select prospective assignment (i.e., beneficiaries are prospectively assigned based on the beneficiary's use of primary care services in the most recent 12- or 24-month period, as applicable) would continue to be required (as currently) to provide the beneficiary notice to all prospectively assigned beneficiaries once during an agreement period.

[34] See §425.312(a)(2)(v).
[35] ACOs that select this option for assignment are assigned beneficiaries before the beginning of the performance year and assignment is then updated quarterly based on the most recent 12 or 24 months of data, as applicable. See §425.400(a)(2).
[36] See §425.312(a)(2)(iii).