MANAGED CARE COMMITTEE
MEETING AGENDA

Wednesday, September 28, 2022
9:30 am – 11:30 am
Conservatory Ballroom A, Conrad Hotel, Washington, DC

DIAL IN INFORMATION:
Phone Number: 301-715-8592 Meeting ID: 821 0186 9143
Passcode: 867445

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II. SURPRISE BILLING **TAB 2 pg. 8**
a. IDR Final Rule
b. SB Request for Information
c. Other

III. GUEST SPEAKER **TAB 3 pg. 10**
a. Deborah Bryant, Senior Advisor, Consumer Support Group
CMS' Center for Consumer Information and Insurance Oversight (INVITED)

IV. MEDICARE ADVANTAGE/MANAGED CARE PRACTICES **TAB 4 pg. 11**
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VII. NEW BUSINESS

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TAB 1

Antitrust Statement
Federation of American Hospitals

To Be Recited By Chairman

I would like to remind everyone that the Federation, its representatives, and its members, are committed to the continued existence of competitive health care delivery systems and markets, and ongoing compliance with all applicable federal and state antitrust laws.

As such, you are reminded that the Federation will not permit at this meeting, or in any other of its forums, any discussion or remarks that suggest or invite anti-competitive conduct among its member hospitals and/or health care systems.

Surprise Billing/Independent Dispute Resolution (IDR) Process

September 2022

- In July 2021, CMS issued an interim final rule (IFR) to implement sections of the *No Surprises Act* relating to the calculation of the qualifying payment amount (QPA), patient notice and consent for post-stabilization services, and a surprise billing complaint process.

- A second IFR to implement the IDR process to resolve payment disputes between providers and payers was issued on September 30, 2021.

- FAH had success with improving the *No Surprises Act* from earlier versions moving through Congress, and we were able to level the field between providers and insurers while protecting patients. The September 2021 IDR rule largely reversed that success by establishing a clear presumption that the initial QPA (which is the median contracted rate) is the correct amount, inconsistent with the law which contemplates that the IDR entity would consider on an equal footing with the QPA several other key factors to ensure adequate payment.
    - This approach aligned with the position of insurers, employers, unions, and consumer/patient groups.

- FAH worked closely with Hill allies and provider partners to counter this IDR provision.
    - The AHA and AMA jointly filed a legal challenge in December 2021 asking the federal DC District Court to declare that the Administration acted unlawfully in promulgating the IDR presumption and to stop enforcement of the rule.
    - The FAH coordinated with the AHA and AMA and led a group of hospital associations in filing an amicus brief in December 2021 support of the lawsuit.
    - After hearing oral arguments in March 2021, DC District Court Judge Leon said it would not be efficient for the Court to issue a decision before the Administration issues its IDR final rule in summer 2022. The case is still pending before the Court.

- The Texas Medical Association also challenged the IDR rule, and in February 2022, a federal District Court in Texas issued a favorable decision. It applies nationwide and concludes that the IDR regulation's heavy-handed presumptive standard, favorable to insurers, is inconsistent with the surprise billing law and does not comply with procedural notice and comment rulemaking requirements.

- Following these efforts, the Administration issued an IDR final rule in August 2022 that eliminates the presumption that the QPA is the correct payment amount, which is a more balanced approach to the IDR process.

- The next key battleground in the IDR process will be whether the QPA transparently captures all relevant information as well as explaining how the QPA may fail in this regard. As the IDR process moves forward, FAH staff is working with members to engage CMS in pushing back on plans' strategies to propose QPAs that are non-transparent and clearly invalid and avoid good faith negotiations with providers through the IDR process.

Hospital Price Transparency

September 2022

- The Patients Right Advocate group conducts the Semi-Annual Hospital Price Transparency Compliance Report. It's third and most recent report issued in August 2022, reviewed 2,000 hospitals and claims that 16 percent of hospitals are in compliance with the hospital price transparency final rule and that 5.1 percent did not post any standard charges at all.
- Two previous reports released by the group allege a 14.6 hospital compliance rate one year after the rule became effective and 5.6 percent six months after the rule became effective.
- The group is advocating for stronger enforcement penalties for hospitals.
- The group's report is highly questionable given that the consulting firm, Milliman, found a 68 percent compliance rate and both organizations' findings varied significantly from CMS – in June 2022, CMS had sent a total of 352 warning letters to noncompliant hospitals requesting corrective action plans and of those citations, CMS said only 157 non-compliant remained noncompliant.
- These types of reports typically generate one-day stories, with CMS enforcement efforts targeted toward outliers that show complete disregard of rule. However, the environment could become more hostile with a possible House Republican majority next year.

<u>CMS Hospital Price Transparency Enforcement</u>

- In June 2022, CMS fined two hospitals for noncompliance the hospital price transparency rules that took effect January 2021 – both were Georgia hospitals within the same system and the fines totaled nearly $1.1 million.
- Before issuing the fines, CMS provided warning notices to both hospitals and requested a corrective action plan, but neither provided a plan.
- Beginning in 2022, the maximum annual penalty for noncompliance for larger facilities increased from $109,500 to over $2 million per hospital.

<u>HHS OIG Hospital Audits</u>

- To evaluate CMS's monitoring and enforcement of the hospital price transparency rule, which took effect January 1, 2021, the HHS OIG announced this month that beginning in 2023 it will review the controls in place at CMS and statistically sample hospitals to determine whether CMS's controls are sufficient to ensure that hospital pricing information is readily available.
    - If hospitals are not in compliance with the transparency rule, the OIG will contact the hospitals to determine the reason for noncompliance and determine whether CMS identified the noncompliance and imposed consequences on the hospitals.

<u>Hospital Price Transparency Legislation</u>

- In June 2022, Senator Braun (R-IN) introduced S. 4414, the *Expose Hospitals Violating Price Transparency* Act, which would require HHS to publish a list of hospitals found not to be in compliance with the hospital price transparency rule.

TAB 3

GUEST SPEAKER

Deborah Bryant, Senior Advisor, Consumer Support Group
CMS' Center for Consumer Information and Insurance Oversight

Bio to follow

Medicare Advantage / Managed Care

September 2022

- The FAH is engaged in a multi-faceted effort to highlight Medicare Advantage (MA) and managed care plan abuses and unfair payment and coverage practices. We continue to raise the issue with multiple policymakers and HHS and CMS leadership in every way we can.
- Our multipronged strategic effort to address MA and managed care abuses includes:
    - Creating metrics of accountability including the submission of a quality measure on Medicare Advantage denials.
    - Pushing for transparency, accountability, and increased oversight over MA plans and their practices.
    - Partnering on research with AHA to inform our advocacy efforts.
    - Educating and engaging policy stakeholders on MA abuses through earned and paid media campaigns.

Legislative Efforts

- On September 14, 2022, H.R. 3173, the *Improving Seniors' Timely Access to Care Act of 2022*, passed in the House. The bipartisan bill establishes several prohibitions, requirements, and streamlined standards relating to prior authorization processes under MA plans.
- The bill aims to:
    - Reduce delays in the prior authorization process by requiring insurers to make it electronic and by tasking HHS with creating a process that enables real-time decisions for routine items.
    - Directs plans to report prior authorization approval rates to CMS, and orders HHS to establish requirements that encourage plans to follow "evidence-based medical guidelines."
- The FAH participated in a large coalition of entities in support of the bill and its House passage. A Senate companion bill, S. 3018, has 43 cosponsors, and the goal is to move it for a Senate vote during the lame duck session of Congress at the end of this year.

HHS' OIG Report on MA Plan Abuses

- In April 2022, the HHS Office of the Inspector General (OIG) released a report finding that MA organizations (MAOs) are often shortchanging patients by denying millions of requests each year for medically necessary care. The report notes that "CMS annual audits of MAOs have highlighted widespread and persistent problems related to inappropriate denials of services and payment."
- In May 2022, the FAH wrote to CMS Administrator Chiquita Brooks-LaSure urging prompt implementation of the OIG's recommendations and further action to protect beneficiaries and address program abuses. The letter notes that the OIG's findings reflect a broader pattern of MAO practices that inappropriately deny, limit, modify, or delay the delivery of or access to services and care for MA beneficiaries.

- In August, CMS released a Request for Information (RFI) on MAO practices and access issues. The FAH submitted comments again urging CMS to make needed changes and to research the potential health disparities in care that may be resulting from MAO practices.

CMS Outreach and Regulatory Efforts

- As part of FAH efforts to hold MA plans accountable, the FAH submitted to CMS a prototype MA quality measure that would publish a plan's Level 1 denial upheld rate for inclusion in an MA plan's star rating. The measure would disincentivize the denial of services or payments that could not be easily supported upon provider or patient appeal.
- The FAH is currently in the early stages of the measurement development process and is engaging in outreach with potential partners to field test and certify the validity of the measure.

Federation of American Hospitals®

Charles N. Kahn III
President and CEO

May 19, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
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Dear Administrator Brooks-LaSure,

The Federation of American Hospitals ("FAH") is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

We are writing to express our strong support for the Centers for Medicare & Medicaid Services ("CMS") taking steps to protect beneficiaries and address program abuses by Medicare Advantage organizations ("MAOs"). We appreciate CMS' concurrence with the recommendations made by the Office of the Inspector General ("OIG") in its recent report, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care" (hereinafter, "OIG Report").[1] MAOs systemically apply problematic operating policies, procedures and protocols in addition to the problematic MAO practices identified in the OIG Report. We therefore urge CMS to exercise its broad oversight authority over MAOs to ensure beneficiaries maintain adequate access to their entitled benefits in the medically appropriate healthcare service setting.

[1] Christi A. Grimm, U.S. Department of Health and Human Services Office of the Inspector General ("OIG"), OEI-09-18-00260, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care" (April 2022), https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf

As part of CMS' efforts to provide guidance to MAOs regarding the appropriate use of MAO clinical criteria for medical necessity reviews, the FAH urges CMS to clarify that MAOs, their downstream risk providers and their contracted hospitalists must provide their beneficiaries with inpatient coverage and providers with inpatient reimbursement: (1) when appropriate under Medicare's Two-Midnight Rule, and (2) when beneficiaries undergo procedures on the inpatient-only (IPO) list. These two Medicare fee-for-service clinical standards should be applied consistently to all Medicare Advantage (MA) beneficiaries since the MA program and the Medicare fee-for-service program serve the same demographic population and each of these beneficiaries are entitled to the same benefits as required by 42 C.F.R. § 422.100. In addition, the FAH urges CMS to address MAO practices that particularly burden beneficiary access to specific types of care or facility types (especially inpatient rehabilitation facilities ("IRFs") and long term care hospitals ("LTCHs") because, as the OIG notes, MAOs may have an incentive to deny such care over cost concerns) by: (1) issuing new guidance to ensure MAOs do not disproportionately burden beneficiary access to particular provider types or care through the use of more restrictive clinical criteria or requests for unnecessary documentation, and (2) undertaking targeted audits focusing on IRF and other specific service types that have a history of inappropriate denials. Finally, the FAH urges CMS to examine and address MAO abuses more broadly to promote MA beneficiary access to timely and appropriate care.

I. Inappropriate MAO Utilization Controls Limit and Delay Beneficiary Access to Care

The OIG Report identifies a pattern by which MAOs apply utilization controls to improperly withhold coverage or care from MA beneficiaries. Specifically:

- *Improper prior authorization denials*. The OIG found that thirteen percent (13%) of prior authorization requests denied by MAOs would have been approved for beneficiaries under original Medicare.

- *Improper denials for lack of documentation*. The OIG found that in many cases, beneficiary medical records were sufficient to support the medical necessity of the services provided.

- *Improper payment request denials*. The OIG found that eighteen percent (18%) of payment requests denied by MAOs actually met Medicare coverage rules and MAO billing rules.

These OIG findings reflect a broader pattern of MAO practices that inappropriately deny, limit, modify or delay the delivery of or access to services and care for MA beneficiaries. FAH members have regularly observed that MAOs abuse prior authorization requirements, maintain inadequate provider networks, use extended observation care, retroactively reclassify patient status (*i.e.*, inpatient versus observation), improperly down code claims, and deploy inappropriate pre- and post-payment denial policies, and even denying claims for previously approved services. These activities are often carried out by way of MAOs'

downstream at-risk physicians and contracted hospitalists. All of these activities limit MA beneficiaries' access to the care to which they are entitled under the Social Security Act.[2]

Many of these harmful practices arise from MAOs' adoption of inappropriate clinical criteria, and the FAH urges CMS to protect beneficiaries by ensuring MAOs adhere to critical Medicare coverage rules. For example, instead of consistently and transparently applying CMS' Two-Midnight Rule, many MAOs use a variety of standards (including unique standards they develop and promulgate on their own) to determine whether a particular hospital stay meets their criteria for an inpatient admission. MAOs deny authorizations for inpatient admissions ordered by physicians and reclassify them as outpatient observation stays with troubling frequency, often using non-transparent, remote means of assessing medical necessity and overriding the treating medical professional's clinical decision. In addition, our members report that MAOs create financial incentives for contracted physicians to change the admission status before discharge and reduce the MAO's payment obligation to hospitals for services and care. Furthermore, members have reported MAO denials of inpatient coverage for procedures included on the Medicare IPO list, which is the single definitive source of guidance as to which procedures must be performed, for patient safety reasons, in an inpatient setting to be covered by Medicare. These practices are not appropriate utilization review activities; instead, they dilute the benefits provided to MA beneficiaries and undermine the benchmarking process used to fund MA coverage and ensure actuarial equivalence. ***The FAH, therefore, continues to recommend that CMS require MAOs and their contracted physicians—including their employed group physicians, downstream at-risk physicians and their hospitalists—follow the Two-Midnight Rule in determining patient status and the medical necessity of an inpatient admission and provide inpatient coverage and payment for each procedure on Medicare's IPO list.*** The consistent application of these requirements across the Medicare program would promote transparency in and fiscal oversight of the MA program.

MAO clinical criteria and review practices may particularly burden beneficiary access to specific types of care, and the FAH supports the OIG's recommendation that CMS undertake targeted audits of particular service types that have a history of inappropriate denials. For example, some MAO plans use proprietary, non-CMS-endorsed standards to determine coverage for IRF services. These standards may direct beneficiaries to less intensive care settings, delaying or denying MA beneficiary access to the intensive, comprehensive, IRF-level care indicated by their condition and reducing access to their entitled benefits. The use of these proprietary standards creates confusion and administrative challenges for beneficiaries and providers and results in an inappropriate misalignment between the treatment of Medicare beneficiaries under the fee-for-service program and those in an MA plan. The OIG's report identified a number of cases in which the MAO improperly denied a request for prior authorization of IRF services. ***The FAH therefore urges CMS to (1) issue new guidance to ensure MAOs do not use more restrictive clinical criteria or request unnecessary documentation, and (2) undertake targeted audits focusing on IRF and other specific service types that have a history of inappropriate denials.***

[2] For further detail, see Federation of American Hospitals, "Re: Needed Improvements to Medicare Advantage Organization Practices," September 1, 2021 (the "September 1 Letter"), attached hereto.

In order to protect MA beneficiaries, the FAH urges CMS to exercise its broad MAO oversight authority and ensure beneficiary access to their entitled benefits by addressing MAO authorization and payment denials of care that meets Medicare coverage rules. As the OIG observed:

> **Denied requests that meet Medicare coverage rules may prevent or delay beneficiaries from receiving medically necessary care and can burden providers.** Even when denials are reversed, avoidable delays and extra steps create friction in the program and may create an administrative burden for beneficiaries, providers, and MAOs. Further, beneficiaries enrolled in Medicare Advantage may not be aware that there may be greater barriers to accessing certain types of health care services in Medicare Advantage than in original Medicare.[3]

The FAH appreciates CMS' concurrence with the OIG's recommendations, including the recommendations to issue new guidance on the appropriate use of MAO clinical criteria in medical necessity reviews and to update CMS' audit protocols to address the issues identified by the OIG.

II. CMS Should Take Steps to Address Broader MAO Abuses and Protect Beneficiaries

In addition to addressing the OIG findings concerning MAOs' inappropriate prior authorization denials, denials for lack of documentation, and payment denials, the FAH urges CMS to exercise its broad oversight authority to curtail a number of other MAO abuses. By way of example, the FAH previously identified in its September 1 Letter the following MAO activities that inappropriately burden providers and may adversely impact beneficiaries:

- **Network Adequacy:** MA beneficiary access to services and care is often more limited than it would appear in an MAO's Health Service Delivery ("HSD") submission or provider directory that a beneficiary reviewed and relied upon during their open enrollment decision making process to choose an MAO. MAOs often use downstream organizations which direct care to a far narrower provider network, rendering network access to certain providers illusory. Downstream organizations are often affiliated with their own contracted or employed physician or provider groups and their sub-capitation arrangements create a financial incentive to direct care to a particular provider or group, creating a *de facto* provider network at the downstream organization level that is far more limited than the MAO's advertised network. The FAH continues to recommend CMS take action to foster MAO network transparency to protect MA beneficiary's access to care by implementing audit protocols to identify and review the adequacy of downstream organizations' provider networks and taking appropriate network enforcement actions for noncompliance with network adequacy standards. In addition, the FAH urges CMS to incorporate network adequacy in the Star Ratings Program.

[3] OIG Letter at 20 (emphasis added).

- **Access to Post-Acute Care:** MA beneficiaries routinely experience inappropriate delays in discharge from the inpatient hospital setting due to MAOs': (1) lack of an adequate post-acute network, (2) lack of post-acute providers in MAOs' networks willing to accept beneficiary discharges, and (3) MAOs' utilization review activities, which include prior authorization to the post-acute setting. When a patient is ready for transfer from an acute-care setting to a post-acute environment (including LTCHs, IRFs, and skilled nursing facilities ("SNFs")), the most appropriate course is the prompt and safe transfer of the beneficiary so s/he may begin to receive post-acute care (e.g., rehabilitation) in the most suitable environment. MAOs, however, often are financially incentivized to prolong beneficiaries' hospital stays (often paid at a case rate such as the MS-DRG system) rather than incurring the additional cost of post-acute provider stays, and may delay discharges based on the lack of available or willing post-acute providers or utilization review activities. In addition, MAO's post-acute networks often do not include an adequate number of post-acute facilities to ensure that the appropriate facility is available and post-acute care is not delayed or disrupted. The FAH recommends CMS require MAOs to demonstrate meaningful network access, including by raising the minimum number of in-network post-acute facilities, establishing a minimum facility-to-beneficiary ratio for in-network IRFs and LTCHs, and monitoring delays in MA beneficiary inpatient hospital discharges due to the lack of capacity among in-network post-acute facilities. In addition, CMS should audit MAO practices associated with approving timely discharges to an appropriate post-acute setting. In contrast to FAH member experiences with MAOs, FAH members generally do not routinely experience these post-acute care issues in the Medicare fee-for-service beneficiary population.

- **Risk Adjustment Claim Encounter Submissions:** The FAH understands MAOs currently include MA encounter data from denied (in part or in full), pended, and underpaid claims in their risk adjustment data submissions to CMS, resulting in increased risk adjustment payments that do not reflect the costs incurred by the MAO. This behavior is inconsistent with the purposes of the Part C Risk Adjustment Program and inflates Medicare spending without any corresponding beneficiary benefit. The FAH urges CMS to limit MA encounter data for the Risk Adjustment Program to data derived from fully paid claims or, in the case of a provider that accepts capitation, provider encounter data.

- **Use of Third-Party Contractors to Perform Audits:** MAOs often hire private contractors on a contingency fee basis to conduct a variety of audits on a pre-payment or post-payment claims basis. These audit types include: (1) charge audits, where the contractors inappropriately remove Medicare covered charges from claims; (2) MS-DRG audits, where the contractors use proprietary software to downgrade the underlying diagnoses necessary to support a DRG by inappropriately removing or rebundling billed ICD-10 codes; and (3) medical record audits, where the contractors question the accuracy of physician documentation regarding the beneficiary's health and associated comorbidities that support the underlying diagnosis and medical necessity. These audits are undertaken without any clinical basis and regularly fail to include an adequate explanation for the contractor's conclusions. Through this process, remote third-party contractors overrule the professional opinion of the treating professionals, despite often lacking the relevant clinical training or expertise. MAOs' delegation to these contractors

frequently creates confusion due to poor communication between MAOs and their contractors. These issues are exacerbated due to convoluted appeal processes, as discussed below. While the FAH acknowledges that MAOs are obligated to conduct reasonable audits, we are concerned that contingency fee audits conducted by MAOs' contractors are improperly motivated by financial incentives, fueling a "bounty hunter" mentality, and inappropriately burdening providers caring for MA beneficiaries. CMS acted several years ago to curb these types of unfair practices under the Medicare fee-for-service recovery audit contractor ("RAC") program and should exercise similar oversight of these practices under the MA program.

- **Appeal Rights:** MA providers' appeal rights are typically governed by their agreements with MAOs. The MAOs' appeals processes are complex, cumbersome, not standard across plans, often not automated, and require significant administrative resources and staffing for health care providers.

- **Improving Transparency and Quality Incentives for MA Stars Ratings Program:** In addition to our recommendations on policy improvements to protect patients in MA, we urge CMS to consider further refinements to its MAO oversight by developing new quality metrics for MAO operations that could be included in the Star Ratings Program. New quality measures should be developed to rate and report on patient access problems related to appeals and denial overturn rates for prior authorization, appeals and overturn rates for payment denials, network adequacy, and service delays. The FAH is currently developing a new MA quality measure concept on Level 1 Appeals to highlight overturn rates for health plans. This measure would supplement the current measure evaluating Level 2 Appeals. We believe such measures would promote competition on these critical access-oriented dimensions of MA plan quality, rewarding and incentivizing better MAO behavior and providing Medicare beneficiaries with critical information on the potential for excessive plan denials for service. We hope to share more on this work with you and your staff soon.

CMS has the statutory authority to address these and other abusive MAO practices as part of its broad oversight authority over MAOs. And, as explained further in the next section, such oversight would not implicate the non-interference clause contained in section 1854(a)(6)(B)(iii) of the Social Security Act or compromise its goals.

III. The Non-Interference Clause Should Be Construed Narrowly

The Social Security Act provides CMS wide latitude to address MAO behavior, and the non-interference prohibitions expressly enumerated in the statute would *not* preclude CMS from taking action regarding MAOs' inappropriate use of clinical criteria to deny or alter care delivery settings, improper actions limiting provider networks, or other abusive measures that inappropriately limit beneficiary access to care and burden providers.

The non-interference clause contains two discrete, narrowly-drawn prohibitions. First, CMS cannot mandate an MAO contract with a specific provider. Second, CMS cannot mandate that an MAO implement a particular price structure within a provider contract. The text of the non-interference clause reads as follows:

> In order to promote competition under this part and part D and in carrying out such parts, the Secretary may not [1] require any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services under this subchapter or [2] require a particular price structure for payment under such a contract to the extent consistent with the Secretary's authority under this part.[4]

Beyond these two express prohibitions, CMS retains its broad regulatory authority – and responsibility – to ensure beneficiaries receive the Medicare benefits to which they are entitled.

The plain text of the non-interference clause has not been expanded by regulation or judicial precedent. To date, we have only identified limited CMS discussion of section 1854(a)(6)(B)(iii) in the context of mandated payment model adjustments for MAOs, which would plainly violate the statute's directive that CMS not "require a particular price structure for payment under" a provider agreement.[5] Along similar lines, CMS recently concluded that a commenter's suggestion that CMS require "payment by the MA organization of certain amounts to a contracted provider" is "within the scope of" actions precluded by the non-interference clause.[6]

The larger context of the MA statutory scheme and legislative history confirm the non-interference clause is a narrowly tailored, targeted provision designed to foster competition rather than to place MAO conduct beyond CMS' regulatory reach. Ever since the Medicare and Medicaid programs were enacted in 1965, CMS has been charged with providing a broad swath of Americans with access to essential quality and affordable health care. The MA program incorporates private, CMS-contracted plans in the Medicare program with the objective of expanding beneficiary choice while leveraging plan competition to improve quality and reduce program costs. The MA non-interference clause and the Part D non-interference clause, are designed to preserve that competition by preventing CMS from setting MA rates or mandating contracting with any particular provider.[7] The legislative history reflects a particular desire to preserve price-based competition among MA plans by prohibiting CMS from setting rates.[8]

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[4] Social Security Act § 1854(a)(6)(B)(iii).

[5] *See* CMS, "Report to Congress: Alternative Payment Models & Medicare Advantage" (July 16, 2019), https://www.cms.gov/medicare/medicare-advantage/plan-payment/downloads/report-to-congress-apms-and-medicare-advantage.pdf; *See also* Centers for Medicare & Medicaid Services (CMS), "Additional Information Regarding the Mandatory Payment Reductions in the Medicare Advantage, Part D, and Other Programs" (May 1, 2013), https://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/Downloads/PaymentReductions.pdf

[6] Medicare Program; Maximum Out-of-Pocket (MOOP) Limits and Service Category Cost Sharing Standards, 87 Fed. Reg. 22,290, 22,380 (April 14, 2022).

[7] In 2003, section 1854(a)(6)(B)(iii) was amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173, § 222, 117 Stat 2066, to extend its requirements to Medicare Prescription Drug Plans, and a corresponding provision was included in the Part D statute at 1860D-11(i).

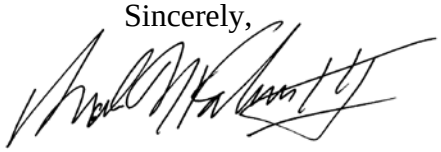
[8] *See* 149 Cong. Rec. S15670-03, S15691, describing legislators' goals in incorporating the non-interference clause with respect to Part D plans: "They said: We believe in competition. . . . Let the private sector negotiate their incentives for the insurers to get lower costs out of the pharmaceuticals. . . . Let that mechanism work. Don't have the head of CMS, the Medicare Director in Washington, DC, dictate prices for everybody. *Let us*

Expanded CMS oversight over the abusive MAO practices described in our September 1 Letter and above would not implicate the non-interference clause or compromise its goals. Indeed, the law is clear that Medicare beneficiaries who enroll in MA plans are entitled to the same benefits, at a minimum, that they would receive if they were enrolled in original Medicare.[9] To that end, CMS retains the authority to ensure MAOs satisfy minimum benefit requirements. By implementing the recommendations we have offered, CMS would ensure MAOs comply with their basic statutory obligation to provide beneficiaries access to timely, adequate, and appropriate care. Such a regulatory response would *promote* meaningful competition between MAOs on the dimensions of quality, value and care delivery while also protecting beneficiaries and providers.

* * *

The FAH appreciates the opportunity to offer these insights. We are committed to working with you to ensure America's seniors in MA plans have improved access and better care. If you have any questions or would like to discuss further, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

Sincerely,



CC: The Hon. Christi A. Grimm, Inspector General, Department of Health and Human Services
Jonathan Blum, Principal Deputy Administrator and COO, CMS
Dr. Meena Seshamani, MD, PhD, Deputy Administrator and Director, Center for Medicare

Attachment

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not set those prices in the Senate. Let us let the marketplace work to squeeze cost and get efficiency out of the system" (emphasis added).

See also 149 Cong. Rec. S15670-03, S15761, "The competition in this bill achieves significant 'bang for the buck' because it relies on drug plans to negotiate discounts. CBO says the private insurance model has a cost management factor of 25 percent-the effect of price discounts, rebates, utilization controls, and other tools that a PDP might use to control spending. By relying on the bargaining power of drug plans, this bill will drive down the costs of prescription drugs."

See also Congressional Budget Office, Letter to the Honorable William H. Frist, MD (January 23, 2004), https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/49xx/doc4986/fristletter.pdf, "CBO estimates that substantial savings will be obtained by the private plans and that the Secretary would not be able to negotiate prices that further reduce federal spending to a significant degree."

[9] *See* S.S.A. §1852(1)(A), "[E]ach Medicare+Choice plan shall provide to members enrolled under this part, through providers and other persons that meet the applicable requirements of this title and part A of title XI, benefits under the original [M]edicare fee-for-service program option".

Attachment

Charles N. Kahn III
President and CEO

September 1, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: Needed Improvements to Medicare Advantage Organization Practices

Dear Administrator Brooks-LaSure:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

The FAH has serious concerns about ongoing and worsening practices of MA plans that are using prior authorization, inadequate provider networks, extended observation care, retroactive reclassification of patient status (i.e., inpatient versus observation), and pre- and post-payment denial policies that are inappropriately limiting Medicare beneficiary access to needed hospital and health care services and improperly delaying or withholding payment for medically necessary services.

These policies have been especially problematic over the past 15 months as hospitals have focused on responding to the COVID-19 pandemic. We appreciate that the Centers for Medicare & Medicaid Services (CMS) August 20, 2021, memo to MA plans "strongly

encouraged" all plans to "waive or relax prior authorization requirements and utilization management processes to facilitate the movement of patients from general acute-care hospitals to post-acute care and other clinically-appropriate settings, including skilled nursing facilities, long-term care hospitals, inpatient rehabilitation facilities, and home health agencies." Our member hospitals in areas surging under this fourth wave of COVID-19 are experiencing the strain of bed and staffing shortages, and CMS' recommendation for MA plans to facilitate more efficient discharge to appropriate post-acute settings will hopefully help them respond to the growing crisis.

But MA plans' problematic practices related to prior authorization and payment denials are not new. In September 2018, the HHS Office of Inspector General (OIG) reported on MA plan prior authorization policies and appeals. The OIG found high rates of overturned prior authorization and payment denials and identified problems related to denials of care and payment. Among other recommendations, the OIG urged HHS to address inappropriate denials and insufficient denial communications. While CMS agreed with the OIG findings and needed changes, these practices have continued and worsened.

Proliferation of Authorizations, Denials, Downcoding, and Reclassifications

The use of various pre-payment and post-payment "tools" by MA plans is proliferating, with a negative impact on patient access and provider payment for services. While some of these tools are meant to ensure program integrity, these plan tactics often go beyond the legitimate scope of these efforts, and instead, result in inappropriate delay of care or denial of payments.

Exacerbating these practices, our members have experienced MA plans that consistently use reviewers who lack appropriate licensure and board certification, such as nurses and general practitioners, to overturn the more qualified clinical medical judgments of board-certified physicians and specialists. This is inconsistent with 42 C.F.R. § 422.590(h)(2), which requires that "[w]hen the issue is the MA organization's denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsidered determination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue . . ."

The 2018 OIG report recommended that CMS reduce the incidence of inappropriate denials by: enhancing oversight of MA contracts and taking corrective action; addressing persistent problems regarding inappropriate denials and insufficient denial letters; and providing enrollees with easy-to-understand and easily accessible information about serious MA plan violations.

The FAH urges CMS to exercise its discretion to follow up on the OIG recommendations and more specifically to consider MA engagement with regard to CMS' Two-Midnight Rule, Medicare Benefit Determination, Prior Authorizations, Appeal Rights, Risk Adjustment Data Submissions, and Network Adequacy.

Two-Midnight Rule

As the FAH has previously shared with CMS, there has been and continues to be a significant trend among MA plans of denying authorizations for inpatient admissions ordered by physicians and reclassifying them as outpatient observation stays instead. MA plans use a variety of standards to determine whether a particular hospital stay meets their criteria for an inpatient admission (sometimes through remote means which often lack transparency), even though determining patient status is a clinical decision that should be made by the medical professional treating the patient. Additionally, our members have had instances where physicians with financial incentives from the MA plan change the admission status before discharge to reduce the payment for care. To address this issue, as we have previously suggested, CMS should require MA plans and MA plan contracted physicians to follow the two-midnight rule in determining patient status. This is the same standard used by CMS for physicians to determine if a particular hospital stay should be covered as an inpatient admission and this standard is equally appropriate for MA beneficiaries.

Medicare Benefit Determination and Payment Rules

Some plans use proprietary non-CMS-endorsed standards to determine coverage for inpatient procedures and inpatient rehabilitation facility (IRF) coverage. Additionally, the Medicare Inpatient-Only (IPO) list (which CMS has recently proposed to in effect "reinstate"), is the single, definitive source of guidance as to which procedures must be performed in an inpatient setting to be reimbursable by Medicare, yet it is not routinely utilized by plans. Similarly, many MA plans do not apply CMS' fee-for-service IRF coverage guidelines, instead using proprietary standards that direct enrollees to less intensive care settings than they need, denying access to the intensive, comprehensive, IRF-level care to which they are entitled. The use of these proprietary standards creates confusion and administrative challenges for beneficiaries and providers and results in misalignment between the treatment of Medicare beneficiaries under the fee-for-service program and those in an MA plan. The FAH urges CMS to ensure that MA plans are following Medicare benefit determination and payment rules.

In addition, MA plans pay third-party private contractors on a contingency fee basis to engage in aggressive audit practices in which they review claims to validate DRG coding and to perform charge audits. Often the DRG validation audits result in a denial or downgrade of the underlying diagnoses necessary to support a DRG. Further, these contractors are now questioning the accuracy of the physician documentation regarding the patient's health and associated comorbidities that support the underlying diagnosis without any clinical basis for doing so. In addition, the charge audits result in the removal of covered charges or the bundling of covered charges for separately reimbursable services. The reviews often are conducted by staff with minimal clinical or billing expertise, do not contain an adequate explanation for the denial or downgraded DRG, and often create confusion due to lack of communication between MA plans and their third-party contractors. These issues are exacerbated due to convoluted and nearly insurmountable appeal processes, as discussed further below. CMS acted several years ago to curb these types of unfair practices under the Medicare fee-for-service recovery audit contractor (RAC) program and should exercise similar oversight of these practices under the MA program.

Authorizations

Our members routinely report delays and inconsistencies with notification and authorization processes for both emergency and elective admissions across MA plans. Some of the more common issues with notifications and authorizations include:

- Inconsistency in the ability of MA plans to implement various notification and authorization systems utilized by providers;
- Lack of transparency and clarity regarding the guidelines plans use to evaluate prior authorization requests;
- Varying authorization and documentation rules across payers and their different products;
- Use of reference numbers that are not authorizations for services and care;
- Inability to rely on prior authorization approvals;
- Delays obtaining prior authorization approval, including for post-acute care, resulting in patients spending more time than clinically necessary in an inpatient setting;
- Delays in access to critical post-acute care and rehabilitation services;
- Limiting peer-to-peer reviews to only permit the attending physician (whose schedule is filled with patient care activities that do not align with also supporting the authorization process) to discuss the provider authorization requests with the plan or only providing a limited time period (e.g., a few hours) in which to have that discussion.

When plans deny the authorization requests, providers struggle to understand why (e.g., based on what guidelines) the request was denied. Sometimes this discontinuity can be addressed without a more formal appeal, but in other instances the provider must enter the extended appeals process. Even when providers make it through the authorization process and receive an approval, they are increasingly finding that some plans do not honor that approval at the time of payment. Plan enrollees and the providers who care for them must be able to rely on authorization determinations. In too many instances, hospitals may not even engage with the plan following an arbitrary denial in light of the time and excessive resource commitment required.

Appeal Rights

Given the challenges described above with authorizations, denials, downcoding and reclassifications, providers (and by extension beneficiaries) are further harmed due to their inability to seek a CMS review. Specifically, the appeal rights for in-network providers are covered by provider participation agreements and are not eligible for appeal to CMS. The appeals processes in participation agreements are complex, cumbersome, not standard across plans, often not automated, and require significant administrative resources and staffing for health care providers. We urge CMS to address these concerns and initiate stricter oversight to ensure Medicare beneficiaries have needed medical and hospital services.

Potential Actions to Mitigate Plan Practices

CMS can take a number of specific actions to reduce the burden of prior authorization, interfere less with patient care, save administrative costs, minimize the need for costly appeals, and better target overuse, waste, and abuse. These include:

- Ensure prior authorization decisions are timely and negative determinations indicate a specific, detailed reason for the denial;
- Improve transparency by providing detailed information on prior authorization policies and tracking and reporting rates of approvals and denials;
- Increase standardization of prior authorization policies, operations, and forms through the use of electronic transmission of prior authorization requests;
- Ensure prior authorization programs adhere to evidence-based medical guidelines and include continuity of care for individuals transitioning between coverage policies;
- Eliminate additional prior authorization for medically necessary services performed during a surgical procedure that already received, or did not initially require, prior authorization; and
- Establish "gold carding," under which payers reduce prior authorization requirements for providers that have demonstrated a consistent pattern of compliance, improving efficiency and resulting in more prompt delivery of health care services.

Risk Adjustment Claim Encounter Submissions

The FAH urges CMS to consider a modification to the Part C Risk Adjustment Program to ensure that risk adjustment payments are made based on data that more accurately reflect the additional expenditures made by MA plans based on members' health status. In particular, the FAH supports limiting MA encounter data to data derived exclusively from paid claims or, in the case of a provider that accepts capitation, provider encounter data. The risk adjustment program is designed to "account[] for variations in per capita costs based on health status,"[1] but at present, we understand that MA plans include MA encounter data from denied, pended, and underpaid claims, which therefore do not reflect the costs incurred by the MA plan. Permitting MA plans to benefit from the inclusion of denied, pended, and underpaid claims through the Part C Risk Adjustment Program is particularly problematic when MA plans deny claims at significantly higher rates than commercial insurance carriers and self-funded group health plans. To put it simply, MA plans should not be able to increase their revenue through the Part C Risk Adjustment Program based on data contained in claims that the MA plan has failed to pay. Limiting the MA risk adjustment data in this way would not place an undue burden on MA plans because the current timelines for submission of this data allows adequate time for the prompt payment of claims prior to the initial data submission deadline, and certainly before the final risk adjustment data submission deadline the following year.

[1] 42 U.S.C. § 1395x-23(a)(3)(A) (emphasis added).

CMS Should Undertake Enforcement Actions for Network Adequacy

While the FAH acknowledges and appreciates that CMS has taken some steps to address inaccurate provider directories, we are disappointed that CMS has not addressed concerns about MA plans' lack of compliance with network adequacy requirements. An MA plan's apparent compliance with network adequacy standards may obscure issues with actual network adequacy and the scope of represented provider options to enrollees within the network, if the MA plan uses downstream organizations to provide administrative and health care services to beneficiaries. Downstream organizations often are affiliated with their own contracted or employed physician or provider groups, and the sub-capitation arrangements create a financial motivation for downstream organizations to direct care to a particular physician or provider group. As a result, these provider groups often become the enrollees' de facto provider network.

Unfortunately, for purposes of demonstrating network adequacy, CMS reviews the network that the plan presents and not at the unidentified sub-network to which many enrollees are relegated. These "networks within a network" often are far narrower than the provider network depicted in the provider directory or the Health Service Delivery (HSD) tables on which CMS based its approval of an MA plan, thus creating a narrower network as the beneficiary moves through the healthcare continuum. Enrollees may have selected a particular MA plan on the basis of its provider network, only to realize later that a downstream organization will discourage enrollees from accessing particular providers. Moreover, the downstream organization's sub-network may not meet the network adequacy standards to which the MA plan is subject.

Additionally, MA patients also experience situations in which a patient stay no longer meets the standards of care for inpatient services, but there is not a medically appropriate post-acute setting available for discharge. This occurs because the MA plan faces no additional financial costs to extend a patient's hospital length-of-stay under the MS-DRG system, but would face additional costs if it transferred the patient to the appropriate post-acute provider of care. Patients have a right under the Medicare program to be treated in an appropriate environment, and this includes a discharge from the inpatient hospital setting when appropriate.

The FAH recommends four actions CMS could undertake to address these concerns. First, CMS should implement audit protocols that identify and review downstream organizations and take enforcement actions, as necessary, for noncompliance with network adequacy standards. Second, CMS should require that MA plans demonstrate meaningful access, including a review of availability of listed post-acute providers that are accepting MA patients. Third, CMS should audit MA plan practices associated with approving timely discharges to an appropriate post-acute care setting. Fourth, CMS should include a standard in the Star Ratings Program to promote the adequacy and stability of an MA plan's network. Specifically, CMS should design a measure to ensure that beneficiaries are aware of the historical problems that any MA plan has had both with the initial adequacy of its networks and with the changes an MA plan has made during the course of a year that affect its networks.

Requiring that MA plans institute these key improvements will promote transparency, efficiency, and timely decision-making, which ultimately will lead to better patient care.

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The FAH appreciates the opportunity to provide these insights into hospital challenges with MA plans and we are committed to working with you to ensure America's seniors in MA plans have improved access and better care. If you have any questions or would like to discuss further, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

Sincerely,

Racial, Ethnic, Socioeconomic, and High-Need Disparities in Enrollment Trends

1. **Racial and ethnic disparities in access to and enrollment in high-quality Medicare Advantage plans**
   Sungchul Park, Rachel M. Werner, Norma B. Coe
   March 27, 2022
   Key Findings:
   - Researchers examined whether differential access to high-rated MA plans was associated with differential enrollment in high-rated plans by race and ethnicity.
   - Data source: The Medicare Master Beneficiary Summary File and MA Landscape File for 2016.
   - On average, racial and ethnic minority enrollees (Black, Asian/Pacific Islander, Hispanic) had higher numbers of MA plans available in their counties of residence than White enrollees, though had lower numbers of high-rated plans (4 stars or more) and higher numbers of low-rated plans (3.5 stars or less).
   - Overall, there was significantly lower racial and ethnic minority enrollment in high-rated plans compared to White enrollees. However, when accounting for county-level MA plan availability, this difference substantially decreased.
   - When looking at Black enrollees, the racial difference reversed when analysis was limited to those in counties with a 5 star plan available, with higher enrollment rates seen in Black beneficiaries than White beneficiaries.
   - The study suggests that racial and ethnic disparities in enrollment in high-quality MA plans may be explained by limited access rather than individual characteristics or enrollment decisions.

2. **Rates of Disenrollment from Medicare Advantage Plans Are Higher for Racial/Ethnic Minority Beneficiaries**
   Steven C. Martino, et al.
   September 2021
   Key Findings:
   - Researchers investigated the differences in rates of voluntary disenrollment from MA plans by race and ethnicity. Voluntary disenrollment is related to negative experiences within the plan and disrupts the continuity of care.
   - Data source: MA plan voluntary disenrollment information from the 2015 Medicare enrollment data file and CMS's Integrated Data Repository (IDR) used to estimate the race and ethnicity of beneficiaries/all control variables.
   - Adjusted rates of disenrollment were significantly higher in Hispanic, Black, and API beneficiaries compared to White enrollees. The study suggests that these differences reflect higher rates of Medicaid eligibility among racial and ethnic minority beneficiaries and the greater opportunities dual-eligible beneficiaries have to disenroll. Additionally, the study authors suggest the differences reflect substantial differences in income and health that are captured both by dual eligibility and by disability status.

- Within states, all 3 racial/ethnic minority groups tended to be concentrated in higher disenrollment plans.
- Within plans, API beneficiaries voluntarily disenrolled considerably more often than otherwise similar White beneficiaries, which was the largest component of API-White difference. The study suggests that this reflects changes in the health or financial circumstances of API beneficiaries or changes in plans' coverage or benefit structures that disproportionately affect API beneficiaries, as well as differences in the way API beneficiaries are served.
- Further research should investigate the causes of higher disenrollment rates for racial/ethnic minority beneficiaries and seek to distinguish the drivers behind leaving MA altogether versus switching to a different plan.

3. **Analysis of Drivers of Disenrollment and Plan Switching Among Medicare Advantage Beneficiaries**
   David J Meyers, et al.
   April 2019
   Key Findings:
   - Researchers investigated the extent to which high-need Medicare beneficiaries switch to and from Medicare Advantage plans, and evaluate drivers of these decisions.
   - Beneficiaries classified as high-need had 2 or more complex chronic conditions or 6 or more chronic conditions from the Chronic Conditions Data Warehouse and used cute or post–acute health care services. Beneficiaries were also considered high-need if they had complete dependency in activities of daily living as indicated in a post–acute care assessment or 2 or more diagnoses indicative of frailty in their inpatient claims, such as failure to thrive or malnutrition.
   - Data source: the Master Beneficiary Summary Files were used to determine MA status. The Healthcare Effectiveness Data and Information Set was used to identify enrollees' specific MA plans. Publicly available star ratings from CMS were used to categorize plan quality.
   - Beneficiaries with complex care needs have higher rates of disenrollment from Medicare Advantage plans than non-high-need enrollees.
   - Among high-need enrollees that switched from MA to traditional Medicare, disenrollment rates were higher in dual eligibles than Medicare-only beneficiaries.
   - High-need enrollees in high-quality plans left Medicare Advantage plans at higher rates than non-high-need beneficiaries in high-need plans.
   - Among low-quality plans, rates of disenrollment among dual-eligibles was almost double those of Medicare-only beneficiaries.
   - For high-need individuals, enrollment in high-quality plans was associated with a 30.1 percent-point reduction in the probability of MA disenrollment.

- The study suggests that star ratings have the highest association with disenrollment trends and that increases in monthly premiums have the highest association with switching to other MA plans.

4. **Association of Health Insurance Literacy With Enrollment in Traditional Medicare, Medicare Advantage, and Plan Characteristics Within Medicare**
   Sungchal Park, Brent A Langellier, David J Meyers
   February 2022
   Key Findings:
   - Researchers examined how health insurance literacy was associated with coverage choices between traditional Medicare and MA as well as within MA, using self-reported measures of health insurance literacy and enrollment data.
   - Enrollment in a Medicare Advantage plan was higher among individuals with higher health insurance literacy than those with lower health insurance literacy. The study's findings suggest disparities in health insurance literacy by socioeconomic status, consistent with prior research. However, further research should specifically examine these associations and explore the underlying mechanisms for each socioeconomic factor.
   - Among MA beneficiaries, those who reviewed or compared coverage options annually were more likely to enroll in plans with 4 to 4.5 stars and plans with monthly premiums of $1 to $50. However, enrollment in plans with 5 stars was 3.8 percentage point lower among those who reviewed or compared coverage options annually than those who did not.
   - Dual eligibles were less likely to review or compare coverage options annually among individuals with low socioeconomic status.

5. **Social and Health-Related Factors Associated with Enrollment in Medicare Advantage in Older Adults**
   Amit Kumar, et al.
   February 2020
   Key Findings:
   - Researchers assessed the characteristics of older Mexican American enrollees in traditional Medicare and MA plans, and the factors associated with disenrollment from TM and enrollment in MA plans using Medicare claims data and insurance status.
   - Data source: the study linked the H-H-EPESE (an ongoing population-based longitudinal study of Mexican Americans 65 years and older residing in Texas, New Mexico, Colorado, Arizona, and California) with the Centers for Medicare and Medicaid Services (CMS) Medicare Beneficiary Summary File (MBSF).
   - Among Mexican American beneficiaries, FFS enrollees were more likely to be socioeconomically disadvantaged (born in Mexico, speak Spanish, lower levels of education, more disability) than MA enrollees.

- However, stronger social support and increased physical limitations were associated with less frequent switching from FFS to MA.
- Older adults living in counties with a high number of MA plans were more likely to switch from FFS to MA compared to adults living in counties with a lower number of plans.
- In those counties with higher numbers of MA plans, beneficiaries with more social support were less likely to switch from FFS to MA.
- The study suggests that older Mexican Americans enrolled in traditional Medicare are more socioeconomically disadvantaged and are more likely to demonstrate poor health status than those enrolled in MA, while emphasizing that increased availability of MA plans at the county level is a significant driver of enrollment in MA plans.
- The study offers a number of possible explanations for their findings.
    - Researchers suggest that older Mexican Americans, who often receive support from family for performing self-care or household activities and other health needs, may use less healthcare services and opt to stay in the same plan.
    - The study found that 25% of MA enrollees had cognitive impairment compared to 41% of FFS enrollees, and that seniors with low cognitive ability may be less likely to make optimal enrollment choices and to be responsive to MA benefit options.
    - 65% of MA enrollees were US-born, suggesting that they are more familiar and comfortable with the US health insurance system than foreign-born individuals.
    - The study further suggests that MA plans may be strategically trying to attract healthier patients and avoid those with more complex needs, as plans may be structured in ways to discourage those with complex conditions from enrolling into MA plans, or to disenroll from them.

6. **Rural Enrollees In Medicare Advantage Have Substantial Rates Of Switching To Traditional Medicare**

   Sungchul Park, David J Meyers, Brent A Langellier
   March 2021

   Key Findings:

   - Researchers examined whether rates of switching from Medicare Advantage to traditional Medicare and vice versa differed between rural and nonrural enrollees. They then examined whether switching was associated with greater dissatisfaction with care access, quality of care, and care costs among rural and nonrural enrollees.
   - Data source: Annual Medicare Current Beneficiary Survey (2010-2016).
   - The study controlled for age, sex, race/ethnicity, education, income, dual eligibility for Medicare and Medicaid, marital status, census region of residence, self-reported comorbidities, number of activities of daily living (ADL) limitations,

and baseline year. The adjusted rates of disenrollment from MA to switch to traditional Medicare were high in both rural and nonrural enrollees. However, the adjusted rate of disenrollment to switch to tradition Medicare for rural enrollees was double that of nonrural enrollees.

- The adjusted rate of MA disenrollment in both groups (rural and nonrural) was notably high among those with poor health status.
- When looking at enrollees with use of services, rural enrollees disenrolled at higher rates than nonrural enrollees. The adjusted rates of disenrollment were even higher among rural enrollees with use of services than among rural enrollees without use of service in 4 out of 5 health care use measures.
- Adjusted rates of disenrollment were consistently higher among rural enrollees than nonrural enrollees that were dissatisfied with access to care. However, there was little difference between rates of disenrollment between rural and nonrural enrollees dissatisfied with out-of-pocket expenses.
- The study suggests that rural MA enrollees may face significant challenges with access to care in their plans, specifically those who require the use of costly services, those with poor self-reported health, and those who reported lower satisfaction with their access to care. The associations, and possible disparities, between disenrollment of MA rural enrollees and demographic characteristics were not investigated by this study.

Racial, Ethnic, and High-need Disparities in Access, Quality of Care, and Experience

7. **Comparison of the Quality of Hospitals That Admit Medicare Advantage Patients vs Traditional Medicare Patients**
   David J. Meyers, Amal N. Trivedi, Vincent More, Momotazur Rahman
   January 2020
   Key Findings:
   - Researchers compare the quality of hospitals that admit MA enrollees with the quality of those that admit traditional Medicare enrollees.
   - Data source: the 100% Medicare Provider and Analysis Review (MedPAR) claims.
   - MA enrollees were more likely to enter an average-readmissions hospital and less likely to enter a low-readmissions or high-readmissions hospital than traditional Medicare enrollees for nonemergent hospitalizations.
   - MA enrollees were more likely to enter a 3 star hospital than a 1 to 2 star hospital or a 4 to 5 star hospital compared to traditional Medicare patients for nonemergent hospitalizations.
   - The researchers observed less substantial differences for emergency admissions.
   - Overall, MA enrollees were more likely to be admitted to average-quality hospitals rather than high or low quality hospitals than traditional Medicare enrollees, suggesting that MA plans may be steering their enrollees to specific hospitals for nonemergent hospitalizations.

8. **Quality of Home Health Agencies Serving Traditional Medicare vs. Medicare Advantage Beneficiaries**
   Margot L Schwartz, Cyrus M. Kosar, Tracy M Mroz, Amit Kumar, Momotazur Rahman
   September 2019
   Key Findings:
   - Researchers examined whether or not MA beneficiaries receive a different quality of care from home health agencies than traditional Medicare beneficiaries.
   - Data source: the Outcome and Assessment Information Set (OASIS) admission assessments of Medicare beneficiaries in 2015 from Medicare-certified HHAs.
   - Medicare Advantage beneficiaries were significantly less likely to receive treatment from high-quality home health agencies compared to TM beneficiaries.
   - The study suggests that MA plans are limiting inclusion of high-quality home health agencies in their networks.
9. **Comparison of the use of the top-ranked cancer hospitals between Medicare Advantage and traditional Medicare**
   Daeho Kim, David J Meyers, Momotazur Rahman, Amal N Trivedi
   October 2021
   Key Findings:
   - Researchers compared the use of top-ranked cancer hospitals for complex cancer surgery between MA and traditional Medicare enrollees.
   - Data source: the 100% CMS Medicare Provider and Analysis Review (MedPAR) file, the Master Beneficiary Summary File (MBSF), and Medicare Advantage Plan Benefit Package (PBP) data.
   - MA enrollees were less likely to use top-ranked cancer hospitals than FFS enrollees by 6.0 percentage points overall.
   - The difference between rates of use of top-ranked cancer hospital varied by care type from 3.5 percentage points for colectomy to 14.3 percentage points for the Whipple procedure.
   - The difference between beneficiaries enrolled in MA plans with out-of-network benefits (OON) and traditional FFS receiving care at top-ranked cancer hospitals was smaller than between those enrolled in plans without OON benefits and FFS beneficiaries.
   - The study suggests that MA enrollees, particularly those with lower OON benefits, may have restricted access to top-ranked hospitals for cancer care compared with traditional Medicare enrollees.

10. **Racial and Ethnic Differences In The Attainment Of Behavioral Health Quality Measures In Medicare Advantage Plans**
    Joshua Breslau, et al.
    October 2018
    Key Findings:

- Researchers examined Healthcare Effectiveness Data and Information Set (HEDIS) data on eight MA behavioral health care quality measures to distinguish racial/ethnic differences within and between MA health plans.
- Data source: MA plan reports on HEDIS measures from CMS.
- With few exceptions, the study observed significant differences in MA plan performance (according to 8 HEDIS measure scores) between racial/ethnic minorities and white beneficiaries. For 7 out of the 8 measure scores, the difference in performance between white and minority beneficiaries exceeded 10 percentage points. These significant differences were observed within plans, between plans, and overall.
- There were significant observed disparities within plans in 20 of 24 comparisons of racial/ethnic minority groups with whites. These disparities varied by plan, with performance being equivalent across racial/ethnic groups in some plans and widely divergent in others.
- The study also observed significant within-plan racial and ethnic disparities in the quality of behavioral health care received by enrollees.

11. **Family and Friend Perceptions of Quality of End-of-Life Care in Medicare Advantage vs Traditional Medicare**
October 2020
Key Findings:

- Researchers examined whether or not quality of care at the end of life as reported by bereaved family and friends differ for people enrolled in MA vs traditional Medicare at the end of life.
- Family and friends of beneficiaries enrolled in MA at the time of death or prior to hospice were more likely to report that care was not excellent and that they were not kept informed compared to traditional FFS.
- Family and friends of MA beneficiaries in a nursing home at the time of death, there was an estimated probability of 77.9% of respondents reporting that care was not excellent compared to 57.2% in traditional FFS.
- The study suggests that MA plans may be restricting their networks to facilities and agencies that are willing to accept lower prices and that consequently may cut staff or other expenses important to the perceived quality of care of these older adults, who are at increased risk.

12. **Medicare Advantage Enrollees More Likely To Enter Lower-Quality Nursing Homes Compared To Fee-For-Service Enrollees**
David J Meyers, Vincent Mor, Momotazur Rahman
January 2018
Key Findings:

- Researchers evaluated the differences in the quality of skilled nursing facilities (SNFs) that Medicare Advantage and traditional Medicare beneficiaries entered in from 2012 to 2014.

- Data source: the 100% Medicare Beneficiary Enrollment Summary File was used for demographic data, and the 100% Minimum Data Set (MDS) file was used for beneficiaries' SNF admission. Enrollee data was then merged with HEDIS to identify each beneficiary's MA plan, by plan contract with CMS.
- After controlling for patients' clinical, demographic, and residential neighborhood effects, traditional Medicare patients have substantially higher probabilities of entering higher-quality SNFs (4 or 5 star ratings by Nursing Home Compare) and those with lower readmission rates, compared to MA enrollees.
- This difference was more significant in lower-quality MA plans than in higher-quality plans.
- The study suggests that MA guides patients to lower-quality facilities.

13. **Racial Disparities in Avoidable Hospitalizations in Traditional Medicare and Medicare Advantage**

Sungchul Park, Paul Fishman, Norma B. Coe
November 2021
Key Findings:

- Researchers examined differences in ambulatory care sensitive conditions (ACSC) hospitalizations and geographic variations between White and Black beneficiaries in traditional Medicare and MA.
- White beneficiaries enrolled in traditional Medicare and MA had similar rates of ACSC hospitalizations.
- Black MA beneficiaries had higher rates of ACSC hospitalizations than Black traditional Medicare enrollees.
- There were racial differences observed in ACSC hospitalizations in both MA and traditional Medicare, with the differences in hospitalization rates being greater between Black and White MA enrollees than in traditional Medicare.
- 95.5% of hospital reference regions (HRRs) had higher rates of ACSC hospitalizations among Black beneficiaries than White beneficiaries in MA, compared to just 54.2% of HRRs in traditional Medicare.
- The study suggests that disparities in access to high-quality primary care are more significant in MA than in traditional Medicare.

14. **Effect of Medicare Advantage on health care use and care dissatisfaction in mental illness**

Sungchul Park
August 2022
Key Findings:

- Researchers examined the effects of MA enrollment on health care use and dissatisfaction with care received among Medicare beneficiaries with mental illness.
- MA enrollment significantly decreased outpatient hospital visits and medical provider visits in enrollees with mental illness compared to traditional Medicare

enrollees. There were no significant changes in inpatient hospital admissions and prescription drug purchases.

- MA enrollment significantly increased dissatisfaction with out-of-pocket expenses by 25.51 percentage points compared to traditional Medicare. However, there were no significant changes in other measures of care dissatisfaction in terms of access to care, quality of care, and prescription medication.
- The study suggests that MA enrollment may lead to low health care use among those with mental illness, indicating efficient care delivery, and that high dissatisfaction with out-of-pocket expenses among MA beneficiaries may imply the use of out-of-network providers to access needed care.

Health-Related Provisions of Inflation Reduction Act of 2022
Summary

On August 7, 2022, the Senate passed an amended version of H.R. 5376, Inflation Reduction Act of 2022 (IRA). The House passed this version on August 12, 2022, which was signed by President Biden on August 16, 2022 (P.L. 117-169). This document summarizes the health-related provisions of the new law.

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Subtitle B—Prescription Drug Pricing Reform

PART 1—LOWERING PRICES THROUGH DRUG NEGOTIATION

Sec. 11001. Providing for Lower Prices for Certain High-Priced Single Source Drugs.
Section 11001(a) of the IRA adds a new Part E to Title XI of the Social Security Act (containing new sections 1191 through 1198) that establishes the Drug Price Negotiation Program.

"Sec. 1191. Establishment of Program
The Secretary of Health and Human Services (HHS) must establish a Drug Price Negotiation Program (or "Program") to reduce Federal and out-of-pocket spending for prescription drugs under Medicare. The Secretary must publish a list of selected drugs, enter into agreements with manufacturers of those selected drugs, and negotiate and renegotiate maximum fair prices (MFP) for each selected drug. (The Secretary must also carry out administrative responsibilities with respect to the Program.) Several key terms are defined in this section as follows:

Initial Price Applicability Year means a year, beginning with 2026.

Price Applicability Period means, for a qualifying single source drug, the period that begins with the initial price applicability year for which a drug is a selected drug and ends with the last year the drug is a selected drug.

Selected Drug Publication Date means, for each initial price applicability year, February 1 of the year that begins 2 years before the initial price applicability year. For example, February 1, 2025 would be the selected drug publication date for the 2027 initial price applicability year. However, as shown in Table 1, the timelines are different for the first initial price applicability year of 2026, in accordance with section 1191(d).

Negotiation Period means, for a selected drug, the period that:
(1) begins on the earlier of (i) the date the manufacturer of the drug and the Secretary enter into an agreement under section 1193 for the drug; or (ii) February 28 following the selected drug publication date for the selected drug; and
(2) ends on November 1 of the year that begins two years before the initial price applicability year (i.e., 9 months after the selected drug publication date for the selected drug).

Manufacturer has the same meaning given that term in the Medicare average sales price payment methodology under section 1847A(c)(6)(A).

Maximum Fair Price means the price negotiated and updated under these provisions for a selected drug during the price applicability period.

Reference Product is defined under the current Public Health Service Act (§351(i)).

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Table 1. Timing and Deadlines in Drug Price Negotiation Program

Provision	Initial Price Applicability Year (IPAY)		
	2026	**2027**	**General rule for 2027+**
Data for determining negotiation-eligible drugs (50 qualifying single-source drugs with highest Medicare expenditures). §1192(d)(1)	6/1/22-5/31/23	Most recent 12 months ending no later than 10/31/24	Most recent 12 months ending no later than 10/31 of year prior to selected drug publication date
Data for ranking negotiation-eligible drugs based on total Medicare expenditures. §1192(b)(1)	6/1/22-5/31/23	Most recent 12 months ending no later than 10/31/24	Most recent 12 months ending no later than 10/31 of year prior to selected drug publication date
Selected drug publication date. §1191(b)(3)	**9/1/23**	**2/1/2025**	**February 1 of the year 2 years prior to IPAY**
Deadline for Secretary to enter into manufacturer agreement. §1193(a)	10/1/23	2/28/25	February 28 following selected drug publication date
Negotiation period start. §1191(b)(4)(A)	10/1/23	2/28/25	February 28 following selected drug publication date
• Deadline for manufacturer to submit required information. §1194(b)(2)(A)	10/2/23	3/1/25	March 1 of the year of the selected drug publication date
• Deadline for initial offer by the Secretary containing proposed maximum fair price and a concise justification. §1194(b)(2)(B)	2/1/24	6/1/25	June 1 following the selected drug publication date
• Deadline for manufacturer response to initial offer. §1194(b)(2)(C)	Not later than 30 days after Secretary's initial offer		
Negotiation period end. §§1191(b)(4)(B), 1194(b)(2)(E)	8/1/24	11/1/25*	November 1 of the year 2 years prior to IPAY*
Publication by Secretary of maximum fair prices. §1195(a)(1)	9/1/24	11/30/25	November 30 of the year 2 years prior to IPAY
Publication by Secretary of explanation of maximum fair prices. §1195(a)(2)	3/1/25	3/1/26	March 1 of the year prior to IPAY
Beginning effective date of maximum fair prices	1/1/26	1/1/27	First day of IPAY

Source: HPA analysis of §11001(a) of the IRA, creating new §§1192-1198 of the Social Security Act.
Notes: For initial price applicability years 2026 and 2027, the provisions apply to only Part D drugs. Beginning in 2028, the provisions also apply to Part B drugs. For 2027 and later, the negotiation begins the sooner of the date listed or the date on which the Secretary and manufacturer enter into an agreement under §1193. Statutory references refer to general timing; however, timing for IPAY 2026 is specified in §1191(d).
* Section 1191(b)(4)(B) states that the negotiation period ends <u>on</u> November 1 of the year that is 2 years prior to the IPAY. However, 1194(b)(2)(E) states that the negotiation period must end <u>prior to</u> November 1 following the selected drug publication date.

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Maximum Fair Price (MFP) Eligible Individual means:

(1) for selected drugs furnished at a pharmacy, through mail order, or by another dispenser, an individual enrolled in a Medicare Part D prescription drug plan (PDP) or enrolled in a Medicare Advantage Prescription Drug plan (MA-PD plan); and

(2) for selected drugs administered by a hospital, physician or other provider of services or supplier, Medicare Part B beneficiaries (including enrollees of Medicare Advantage plans) to the extent the selected drug is covered under such parts.

Thus, these negotiation provisions will affect Medicare beneficiaries' Part B drugs (including those obtained through Medicare Advantage plans) and Part D drugs (including those obtained through Medicare Advantage plans).

Total Expenditures:

- For Part D, includes total gross covered prescription drug costs (defined in current §1860D-15(b)(3), which does not include administrative costs but includes costs directly related to dispensing); and
- For Part B, excludes expenditures for drugs and biologicals that are bundled or packaged into the payment for another service.

Unit means the lowest identifiable amount of a drug or biological that is dispensed or furnished.

"Sec. 1192. Selection of Negotiation-Eligible Drugs as Selected Drugs

Each year, the Secretary must identify a certain number of brand-name drugs that are found to lack price competition and that are high spend Medicare drugs that will be subject to the Program's negotiation process. In general, the Secretary's annual identification of these drugs occurs in the following order, with more detailed definitions below:

- Identify **qualifying single source drugs** (§1192(e));
- From qualifying single source drugs, identify the **negotiation-eligible drugs**, which are (§1192(d)):
  - For initial price applicability year 2026 onward, the 50 qualifying single source drugs with the highest Medicare expenditures under Part D; and
  - For initial price applicability year 2028 onward, the 50 qualifying single source drugs with the highest Medicare expenditures under Part B.
- From negotiation-eligible drugs, **selected drugs** published on the Secretary's list in an initial price applicability year that will be subject to the Program's negotiation process (§1192(c)). Selected drugs are the negotiation-eligible drugs with the highest rankings in terms of total Medicare Part D and/or Part B expenditures (§1192(b)(1)(B)). The number of selected drugs for each initial price applicability year is specified as follows (§1192(a)):
  - For 2026, up to 10 Part D drugs;
  - For 2027, up to an additional 15 Part D drugs;
  - For 2028, up to an additional 15 Part D or Part B drugs; and
  - For 2029 and subsequent years, up to an additional 20 Part D or Part B drugs.

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Qualifying Single Source Drug means:

- An FDA-approved drug product[1] that is not the listed drug for any generic drug and for which at least 7 years have elapsed since the date of its approval; or
- A licensed biological product[2] that is not the reference product for any biosimilar and for which at least 11 years have elapsed since the date of that license.

The practical effect of this definition means that single source drugs will have at least 9 years before being subject to price negotiation and that biologicals will have at least 13 years before being subject to negotiation.

There is a special rule for authorized generic drugs[3] under which the authorized generic drug and the listed drug (or reference product) are treated as the same qualifying single source drug for purposes of the Program. Authorized generic drugs are generic drugs that are produced (or authorized to be produced) by the same manufacturer as the brand-name drug, often beginning during the brand-name drug's period of exclusivity (i.e., before other manufacturers can produce a generic version). If the drug is only available as the brand-name and authorized generic drug, then it is treated as the same qualifying single source drug.

The term qualifying single source drug excludes plasma-derived biological products, certain orphan drugs (those for which the only approved indication(s) is to treat only one rare disease or condition), and low spend Medicare drugs. Low spend Medicare drugs are those with total expenditures under Medicare Part B and Part D of less than the following:

- For initial price applicability year 2026, $200 million;
- For initial price applicability year 2027, the prior-year amount ($200 million) indexed for inflation;[4] and
- For subsequent years, the prior-year amount indexed for inflation.[5]

The Medicare Part B and Part D expenditure data for determining low spend Medicare drugs are the same as the first row in Table 1, as follows:

- For initial price applicability year 2026, expenditure data from June 1, 2022 to May 31, 2023;
- For initial price applicability year 2027, expenditure data from the most recent 12 months ending no later than October 31, 2024; and
- For subsequent years, expenditure data from the most recent 12 months ending no later than October 31 of the year prior to the year of the drug publication date.

[1] Approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act.
[2] Licensed under section 351(a) of Public Health Service Act (PHSA).
[3] An authorized generic drug is one that has been approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug.
[4] Using CPI-U from June 1, 2023 to September 30, 2024.
[5] Using CPI-U for the 12-month period ending on September 30 of the year prior to the year of the selected drug publication date.

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Negotiation-eligible Drug generally refers to a **qualifying single source drug** that is either:

- Among the 50 covered part D drugs with the highest total expenditures under Medicare Part D, beginning with the initial price applicability year of 2026; or
- Among the 50 Part B drugs with the highest total expenditures under Medicare Part B, beginning with the initial price applicability year of 2028.

As shown above in the first row of Table 1, to calculate Part B and Part D total expenditures, data are generally for the 12-month period that ends before October 31 of the year prior to the selected drug publication date for the following year.[6] Data must be aggregated across dosage forms and strengths; the determination may not be made on the specific formulation or package size or type of the drug.

In determining which drugs are determined negotiation-eligible drugs for a year, the Secretary may not consider or count any drug that is already a selected drug.

Small biotech drugs are excluded from the definition of negotiation-eligible drugs for the first three years. For initial price applicability years of 2026, 2027 and 2028, Part B and Part D qualifying sole source drugs are not considered to be negotiation-eligible drugs if they meet the following criteria:

- Expenditures for the drug in 2021 do not exceed 1 percent of the total expenditures under Part B or Part D (respectively) for all Part B drugs or covered Part D drugs (respectively); and
- Expenditures for the drug in 2021 equal at least 80 percent of the total expenditures for all Part B drugs or all covered Part D drugs (respectively) of the manufacturer.

This exception does not apply to new formulations of the qualifying single source drug. There are special aggregation rules and acquisition rules for manufacturers in applying this exception.

Selected Drugs. From the drugs identified as negotiation-eligible drugs for each initial price applicability year, the Secretary must do the following:

- Rank (from high to low) the combined list of negotiation-eligible drugs for a year by total expenditures under Medicare Parts B and D; and
- Select the drugs with the highest rankings. However, because Part B drugs are excluded from the Program during the 2026 and 2027 initial price applicability years, the ranking for those years only applies with respect to total expenditures for Part D drugs.

As previously stated, the number of selected drugs for each initial price applicability year is as follows:

- For 2026, up to 10 Part D drugs;
- For 2027, up to 15 additional Part D drugs;
- For 2028, up to 15 additional Part D or Part B drugs; and
- For 2029 and subsequent years, up to 20 additional Part D or Part B drugs.

[6] The exception is for the initial price applicability year of 2026, for which the data must be from the period of June 1, 2022 to May 31, 2023.

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Selected drugs are subject to negotiation during the negotiation period for the initial price applicability year (and to renegotiation during subsequent years during the price applicability period), with the following exception. The manufacturer of a selected drug that becomes subject to competition before or during the negotiation period applicable to the selected drug for an initial price applicability year will not be required to negotiate prices under the Program for that selected drug. Nonetheless, the drug will continue to be considered a selected drug under the Program for purposes of the number of negotiation-eligible drugs published on the list for that initial price applicability year.

A drug is no longer considered a selected drug with respect to a year when there is at least one competitor product on the market.

As noted above, in determining which drugs are determined negotiation eligible for an initial price applicability year, the Secretary may not consider or count any drug that is already a selected drug. Thus, a qualifying single source drug that is a selected drug for an initial price applicability year may not be included in the list of negotiation-eligible drugs for another initial price applicability year. The intention appears to be to avoid counting a previously selected drug toward the maximum number of negotiation eligible drugs that may be selected for a subsequent year, thereby increasing over time the number of drugs selected for negotiation under the Program.

"Sec. 1193. Manufacturer Agreements

The Secretary must enter into an agreement with each manufacturer of a selected drug for a price applicability period fairly quickly (i.e., within approximately a month of the selected drug publication date). Each agreement will require the parties to negotiate a maximum fair price (MFP) for the drug during the initial price applicability year under the process established under section 1194. The agreement and its MFP will continue unless the drug is no longer a selected drug (i.e., until there is competition on the market for the selected drug) or if the drug meets criteria for the renegotiation of its MFP under the process established under section 1194(f). Under the agreement, manufacturers must provide access to the MFP for a selected drug to MFP eligible individuals who are MA-PD or Part D plan enrollees at the point-of-sale (i.e., either at the pharmacy, through mail order or other prescribers) and to hospitals, physicians and other providers and suppliers with respect to MFP eligible individuals during the price applicability period.

Manufacturers must submit information on the drug's non-Federal average manufacturer price (non-FAMP), which is the average price wholesalers pay for drugs distributed to purchasers outside the federal government,[7] as well as "information that the Secretary requires to carry out the negotiation (or renegotiation process)".

[7] At 38 USC 8126(h)(5), the term "non-Federal average manufacturer price" means, with respect to a covered drug and a period of time (as determined by the Secretary [of Veterans Affairs]), the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period, but not taking into account (A) any prices paid by the Federal Government; or (B) any prices found by the Secretary to be merely nominal in amount.

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Information submitted to the Secretary pursuant to a manufacturer agreement is considered proprietary information and may only be used for purposes of the Program; the Secretary may disclose that information to GAO but only for purposes of carrying out the Program. Manufacturers must comply with requirements imposed by the Secretary.

To prevent duplication with 340B, when the 340B ceiling price is lower than the maximum fair price, the manufacturer is not required to provide the maximum fair price for maximum fair price eligible individuals who are also eligible for the drug through a 340B covered entity. On the other hand, when the maximum fair price is lower than the 340B ceiling price, the manufacturer is required to provide access to the maximum fair price in a nonduplicated amount for maximum fair price eligible individuals who are also eligible for the drug through a 340B covered entity.

"Sec. 1194. Negotiation and Renegotiation Process
As noted above, a manufacturer of a selected drug and the Secretary must negotiate (and renegotiate as applicable) the MFP for the drug during the price applicability period. The Secretary will establish a consistent methodology for those negotiations that aims to achieve the lowest MFP for a selected drug.

Negotiation Process. For the initial price applicability year for a selected drug, the elements of the negotiation are as follows (with timing shown in Table 1 above):

- Manufacturer submission of information. A manufacturer must submit to the Secretary information on the non-FAMP for the drug and year and all other information required by the Secretary to carry out the negotiation process.
- Initial offer by Secretary. The Secretary makes an initial written MFP offer which shall include a concise justification of the following factors used to develop the MFP offer.
- Factors. The Secretary must consider the following factors, as applicable to the drug, for determining offers and counteroffers:
    - Manufacturer-specific data:
        - Research and development costs of the drug and the extent to which those costs have been recouped;
        - Current unit costs of production and distribution;
        - Prior federal financial support;
        - Data on patents; and
        - National sales data
    - Evidence about alternative treatments:
        - The extent to which the drug represents a therapeutic advance as compared to existing alternatives (and their costs);
        - Prescribing information of the drug and therapeutic alternatives;
        - Comparative effectiveness of the drug and therapeutic alternatives (taking into account effects on subpopulations such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations);[8]

[8] The Secretary may not use evidence on comparative effectiveness in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than an individual who is younger, nondisabled, or not terminally ill.

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        - The extent to which the drug and therapeutic alternatives address unmet medical needs.
- Manufacturer response to initial offer. The manufacturer has 30 days to respond (either accept or make a counteroffer that must be in writing and be justified also based on the factors above). The Secretary must respond in writing to a counteroffer; except for initial price applicability year 2026, all negotiations must conclude before November 1 of that year.

The Secretary is not permitted to agree to an MFP that exceeds the ceiling or is less than the floor for the selected drug and year involved, as described below.

MFP Ceiling. Price ceilings are based on the lower of what the statute calls the Subparagraph (B) amount and the Subparagraph (C) amount. Those terms are defined as follows:

- Subparagraph (B) amount:
    - For Part D drugs, the sum of the plan specific enrollment weighted amounts for each PDP or MP-PD plan. This is essentially the national average price[9] paid by all Part D and MA-PD plans taking into account each plan's enrollment.
    - For Part B drugs or biologicals, the lesser of the volume-weighted average sales price (ASP) and the wholesale acquisition cost (WAC) for the year prior to the selected drug publication date.
- Subparagraph (C) amount is based on the non-FAMP multiplied by one of the following percentages:
    - 75% for "Short-Monopoly Drugs and Vaccines" (i.e., drugs that are neither extended-monopoly drugs nor long-monopoly drugs);
    - 65% for "Extended-Monopoly Drugs" (i.e., drugs that are on the market for at least 12 and less than 16 years—other than vaccines licensed under section 351 of the PHSA and selected drugs before initial price applicability year 2030); and
    - 40% for "Long-Monopoly Drugs" (i.e., drugs that are on the market for more than 16 years—other than vaccines licensed under section 351 of the PHSA).

For 2026, the non-FAMP is based on 2021, increased by CPI-U to the year ending before the selected drug publication date (i.e., 2025). For 2027 and subsequent years, the non-FAMP is the lesser of (i) the non-FAMP for such drug in 2021 increased by CPI-U to the year ending before the selected drug publication date or (ii) the non-FAMP for the drug for the year ending before the selected drug publication date.

Temporary Floor for Small Biotech Drugs. For a small biotech drug for which the first initial price applicability year of a price applicability period is 2029 or 2030, the MFP may not be less than 66 percent of the non-FAMP for the drug in 2021 increased by CPI-U to the year ending before the selected drug publication date. (As described above, small biotech drugs are excluded from the definition of negotiation-eligible drugs altogether for initial price applicability years of 2026, 2027 and 2028.)

[9] The negotiated price net of all price concessions received by the plan or the pharmacy benefit manager (PBM) on behalf of the plan.

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Renegotiation Process. Beginning with 2028, the Secretary must establish a renegotiation process for a renegotiation-eligible drug during the price applicability period for that selected drug. A renegotiation-eligible drug is a selected drug (i) that has a new indication added; (ii) that was not an extended or long-monopoly drug but becomes an extended-monopoly drug; (iii) that becomes a long-monopoly drug, or (iv) for which there is a material change (based on any of the factors described earlier).

Each year, the Secretary must renegotiate the MFP for renegotiation-eligible drugs that:

- Become extended-monopoly drugs,
- Become long-monopoly drugs, and
- Other drugs (i.e., those with new indications or a material change in factors) for which the renegotiation will likely result in significant changes in the MFP.

The renegotiation process must be consistent with the negotiation process described above, including the application of the ceiling and floor for the MFP. If a generic drug or biosimilar product for a selected drug is approved or licensed before or during the renegotiation process, the selected drug is no longer subject to the renegotiation process.[10]

"Sec. 1195. Publication of Maximum Fair Prices

As shown in Table 1, the Secretary must publish the MFP for a selected drug by November 30 of the year that is two years before the initial price applicability year (e.g., November 30, 2025 for the 2027 initial price applicability year)—except for the 2026 initial price applicability year, when the MFP must be published by September 1, 2024.

The Secretary must publish an explanation for the MFP negotiated for a selected drug by March 1 of the year that precedes the initial price applicability year (e.g., March 1, 2025 for the 2026 initial price applicability year).

For subsequent years, the Secretary will publish the MFP for the selected drug either as adjusted for inflation by the CPI-U or as renegotiated. The date of publication is not later than November 30 of the year that is two years before the subsequent year (e.g., November 30, 2025 for 2027).

If the MFP for a selected drug is determined after the regular date of publication of the MFPs for selected drugs, the MFP must be published within 30 days of its determination.

"Sec. 1196. Administrative Duties; Coordination Provisions

This section requires the establishment of procedures for the following purposes:

- To apply the MFP before any discounts or coverage (or financial assistance) for prescription drug coverage for MFP eligible individuals;
- To compute the MFP across different strengths and dosage forms;
- To apply the Program for the benefit of MFP eligible individuals;

[10] Section 1194(g) attempts to describe when the MFP for a selected drug, as negotiated or renegotiated, takes effect. However, the content and cross-references in this provision do not appear to clearly correspond to any of the other provisions in section 1194. It may have been intended to be part of another section. This will likely be clarified in rulemaking.

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- To establish the negotiation and renegotiation processes;
- To establish a process for manufacturers to submit information to the Secretary;
- To share information with the Treasury for purposes of applying any excise tax for noncompliance (see below); and
- To establish procedures for the special aggregation rules and acquisition rules for manufacturers in applying the exception for small biotech drugs during 2026, 2027, and 2028.

The Secretary must monitor manufacturers' compliance under the agreement and establish a mechanism for reports of noncompliance. Any violations are subject to enforcement under the Internal Revenue Code (IRC) excise tax provisions (i.e., new §5000D of the Internal Revenue Code, described below) or civil monetary penalties under section 1197.

"Sec. 1197. Civil Monetary Penalty

Civil monetary penalties (CMP) may be imposed on a manufacturer of a selected drug subject to a manufacturer agreement for violating the requirement to provide access to the selected drug at or below the MFP for the year involved to MFP eligible individuals or to providers of services (including hospitals) and suppliers (including physicians) with respect to those individuals. The CMP will be determined by—

- multiplying the number of units of the selected drug furnished, dispensed or administered during the year involved by the difference between (i) the price at which the selected drug was made available by the manufacturer for the year involved to the individual, provider of services or supplier and (ii) the MFP for that drug and year; and
- multiplying that product by ten.

Additionally, a CMP of up to $1 million for each day of a violation may be imposed for failure to comply with administrative requirements, including the provision of information, to carry out the Program.

A CMP may also be imposed on a manufacturer for knowingly providing false information for purposes of the special aggregation rules and acquisition rules for manufacturers in applying the exception for small biotech drugs during 2026, 2027, and 2028. This CMP is equal to $100,000,000 for each item of false information.

"Sec. 1198. Limitation on Administrative and Judicial Review

Administrative and judicial review are prohibited for the determination of the following:

- A unit, with respect to a drug or biological product;
- Selected drugs;
- Negotiation-eligible drugs;
- Qualifying single source drugs;
- Maximum fair price; and
- Renegotiation-eligible drugs.

Section 11001(b) of the IRA makes a number of conforming amendments to the Medicare and Medicaid statutes, as follows.

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Medicare Part B Average Sales Price (ASP) Methodology: Substitutes the MFP for a selected drug during the price applicability period that is payable under section 1847A (ASP Methodology) in lieu of ASP (or WAC) for that drug or biological.

Medicare Advantage (MA): Prohibits MA plans from charging cost-sharing for selected drugs in excess of the amount of cost-sharing for those selected drugs that would apply under Medicare Part B based off the MFP for the selected drug. Also requires MA plans to provide information, including price information, to the Secretary on selected drugs covered under the plan for purposes of the negotiation and renegotiation processes under the Program.

Medicare Part D: Waives the noninterference clause with respect to selected drugs, and requires that negotiated prices for payment of selected drugs may not exceed the sum of the MFP during the price applicability period and any dispensing fees. Also requires coverage under the plan of each selected drug that is a covered Part D drug during the price applicability period for the plan year, although the plan is not prohibited from removing the selected drug from a formulary (if permitted under current regulations). Further requires plan sponsors to provide information, including price information, to the Secretary on selected drugs covered under the plan for purposes of the negotiation and renegotiation processes under the Program.

Exemptions for Essential Drugs: Under current law, manufacturers of drugs treated by the Secretary as being essential to the health of beneficiaries are exempt from certain requirements under Part D, Part B, and Medicaid. Those exemptions will not apply if the manufacturer is subject to the new excise tax under 5000D of the Internal Revenue Code for compliance violations of the Drug Price Negotiation Program.

Medicaid Drug Rebate Program: Requires the MFP for a selected drug during the price applicability period to be taken into account in calculating the best price for the drug under the Medicaid rebate program and for purposes of other provisions of law that refer to the Medicaid best price definition, including prices negotiated for the selected drug under MA-PD and Part D PDP plans. However, any reduction in price for the MFP would not be reflected in average manufacturer price (AMP).

Section 11001(c) of the IRA states that the Secretary shall implement this section 11001—including amendments made by this section for 2026, 2027, and 2028—by program instruction or other forms of program guidance.

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Sec. 11002. Special Rule to Delay Selection and Negotiation of Biologics for Biosimilar Market Entry.

This section makes changes to the Drug Price Negotiation Program established in the prior section by adding a new subparagraph (f) to section 1192. Under this special rule, the Secretary may delay—by no more than 2 years—a biological from having an MFP set under the Program if the Secretary determines there is a high likelihood that a biosimilar biological product ("biosimilar" for purposes of this summary) will be both licensed (approved by the FDA) and marketed (sold in the marketplace) within 2 years. This section details how a manufacturer may request the delay under this special rule, the conditions that must be met for the Secretary to make a determination that the biological qualifies, the effects of the delay, and what happens if the Secretary finds there is no longer a high likelihood of a biosimilar being licensed and marketed within the required time period.

Application for Special Rule

A biological product may qualify for this special rule if:

- It is an extended-monopoly drug;[11]
- In the absence of this rule, it would be a selected drug under the Program; and
- The Secretary determines there is a high likelihood that a biosimilar will be both licensed and marketed within 2 years of the selected drug publication date.

The special rule's initial 1-year delay can only be applied if that delay is requested of the Secretary by a manufacturer of a biosimilar prior to the selected drug publication date in which the biological product would have been included. The special rule's second (and final) 1-year delay can only be applied if that delay is also requested of the Secretary by a manufacturer of a biosimilar biological product—prior to the 1-year anniversary of the selected drug publication date in which the biological product would have been included.

The request(s) must be submitted at a time and in a form specified by the Secretary, and must contain the following:

- Information necessary for the Secretary to make the determination, as specified by the Secretary and including the following (to the extent available):
    - The manufacturing schedule for the biosimilar as submitted to the FDA for its review of the biosimilar application;
    - Disclosures in certain required filings with the Securities and Exchange Commission (SEC) about capital investment, revenue expectations and actions taken by the manufacturer that are typical of the normal course of business in the year (or two) before marketing the biosimilar that pertain to such marketing or comparable documentation distributed to the shareholders of privately held companies;

[11] An extended-monopoly drug is a drug that has been on the market for at least 12 and less than 16 years—excluding vaccines licensed under section 351 of the PHSA and selected drugs before initial price applicability year 2030.

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- Agreements between the manufacturers of the reference product and the biosimilar relating to the licensing of the biosimilar that are required to be filed with the Federal Trade Commission (FTC) or the Assistant Attorney General; and
- Any follow-up information requested by the Secretary.

Implementation of Special Rule

The Secretary may delay a biological from having an MFP set under the Program if the Secretary determines there is a high likelihood that a biosimilar will be licensed and marketed within 2 years of the otherwise applicable selected drug publication date. There is a **high likelihood** if the Secretary finds that:

- An application for biosimilar licensure has been accepted for review or approved by the FDA; and
- The information submitted to the Secretary (described above) provides clear and convincing evidence that such biosimilar will be marketed within the 2-year period of the special rule's delay (or within the remaining 1-year period, in the case of a possible extension of the delay for the second 1-year period).

If the Secretary makes the high-likelihood determination, a 1-year delay applies for the reference biological from being a selected drug. After that initial 1-year delay, if the biosimilar has not been licensed and marketed, the Secretary will (at the request of the biosimilar manufacturer):

- Reevaluate whether or not there is a high likelihood that the biosimilar will be licensed and marketed during the remainder of the 2-year period; and
- Evaluate whether, on the basis of clear and convincing evidence, the manufacturer has made significant progress (as determined by the Secretary) toward both licensure and marketing of the biosimilar, based on updated information provided to the Secretary regarding agreements related to the biosimilar filed with the FTC or the Assistant Attorney General, or additional information and documents requested by the Secretary necessary to make such determination.

After that initial 1-year delay, if the Secretary determines there is <u>not</u> a high likelihood that the biosimilar will be licensed and marketed within the remaining timeframe, or that there has not been significant progress toward such licensing and marketing, then the reference biologic will be a selected product for the next year (that is, it only obtained a 1-year delay from being a selected drug) and will be required to pay a rebate (described below) related to that 1-year delay.

On the other hand, if after that initial 1-year delay the Secretary determines there <u>is</u> a high likelihood that the biosimilar will be licensed and marketed within the remaining timeframe and that there has been significant progress toward such licensing and marketing, then the reference biologic will not be a selected product for the next year (that is, it obtains the entire 2-year delay from being a selected drug). If during that entire 2-year period a biosimilar was neither licensed nor marketed, not only will the reference biological become a selected drug after the two-year delay, but the manufacturer must also pay a rebate for the 2-year delay, described below.

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The language then reiterates that in no case shall the Secretary delay for more than 2 years the inclusion of a biological from being on the published list of selected drugs. Other limitations on delays include the following:

- If a reference biological was delayed from the list by one year and, if it would have been on the list, its status would have changed to a long-monopoly drug (that is, on the market for more than 16 years), the Secretary in no case may provide a second 1-year delay.
- No delay is permitted for a biological for which more than 1 year has elapsed since the biosimilar was licensed but still has not begun marketing.
- No delay is permitted if the Secretary determines that the manufacturer of the biosimilar either (I) is the same as the manufacturer of the reference biological, or (II) based on information provided to the Secretary regarding agreements related to the biosimilar filed with the FTC or the Assistant Attorney General, has entered into an agreement with the manufacturer of the reference product that requires or incentivizes the biosimilar manufacturer to submit a delay request or restricts the quantity of the biosimilar that may be sold in the United States over a specified period of time.

Rebate

If a manufacturer's reference biological was delayed from being a selected drug but that delay ended with no biosimilar being approved and marketed (or the Secretary did not extend the delay beyond the first 1-year delay for the reasons described earlier), the manufacturer of the reference biological must pay a rebate to the federal government for the period of the delay. The rebate will be paid at such time and in such manner as determined by the Secretary.

The amount of the rebate will be the following estimated amount:

- For Part D, 75 percent of the amount by which the AMP for the biological exceeds the MFP that would have been negotiated (increased by CPI-U for the second year, if applicable), for the number of units dispensed under Part D—determined for each calendar quarter during such price applicability period; and
- For Part B, 80 percent of the amount by which the otherwise applicable Part B payment for the biologic (under the Medicare average sales price payment methodology under section 1847A(b)) exceeds the MFP that would have been negotiated (increased by CPI-U for the second year, if applicable), for the number of units administered and furnished under Part B[12]—determined for each calendar quarter during such price applicability period.

If a biologic for which a rebate must be paid becomes a long-monopoly drug at the time of its inclusion on the published list of selected drugs, the following calculation will be used in place of the MFP in calculating the rebate owed: 65 percent of the average non-FAMP generally for 2021, increased by CPI-U from September 2021 to September of the year prior to the selected drug publication date that would have applied if not for the delay.

[12] The number of units under Part B here excludes units that are packaged into the payment amount for an item or service and are not separately payable under Part B.

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These rebates for Part B and Part D biologics will be deposited into the (Part B) Federal Supplementary Medical Insurance Trust Fund and the (Part D) Medicare Prescription Drug Account, respectively.

Any manufacturer that fails to comply with these rebate requirements will be subject to CMPs of 10 times the amount of the rebate the manufacturer failed to pay.

Section 11002(c) of the IRA states that the Secretary shall implement this section 11002—including amendments made by this section for 2026, 2027, and 2028—by program instruction or other forms of program guidance.

Sec. 11003. Excise Tax Imposed on Drug Manufacturers During Noncompliance Periods.

If a manufacturer refuses to enter into negotiations (or renegotiations) after being selected by the Secretary or if the manufacturer leaves the negotiation (or renegotiations) before a maximum fair price is agreed to, then the manufacturer will be assessed an excise tax levied on its annual gross sales for the drug based on the number of days out of compliance. The excise tax— created in a new section 5000D of the Internal Revenue Code—will also apply for failure by the manufacturer to submit information required by the Secretary by the due date; the excise tax will apply for each day after the Secretary certified the information is overdue and will end on the date the information is submitted.

For days that would otherwise count in the noncompliance period, the tax is suspended beginning when the Secretary has received notice of terminations of all applicable agreements[13] of the manufacturer and when none of the drugs of the manufacturer are covered by a Part D agreement.[14]

The assessment begins at 65 percent and increases by 10 percentage points every quarter the manufacturer is out of compliance to a maximum of 95 percent.

Sec. 11004. Funding.

Appropriates $3,000,000,000 to CMS for fiscal years 2022 to carry out the provisions of this part, including the Drug Price Negotiation Program, the enforcement provisions, and the conforming amendments to the Medicare and Medicaid statute. Funds are available until expended.

[13] Specifically, the Medicare coverage gap discount program under section 1860D-14A, the new manufacturer discount program created by the IRA as a new section 1860D-14C of the Social Security Act, and the Medicaid rebate program.
[14] Specifically, the Medicare coverage gap discount program under section 1860D-14A and the new manufacturer discount program in section 1860D-14C.

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PART 2—PRESCRIPTION DRUG INFLATION REBATES

Sec. 11101. Medicare Part B Rebate by Manufacturers

This section establishes a mandatory rebate program for all manufacturers of "Part B rebatable drugs" if the manufacturer has raised the price of the drug above the rate of inflation since July 2021. This rebate program begins with the first calendar quarter of 2023.

Part B Rebatable Drugs

A Part B rebatable drug is defined to mean any single source drug or biological (including most biosimilars) that is paid under Part B. However, the following drugs and biologicals are excluded from the definition and are not subject to mandatory rebate program:

1. Vaccines.
2. Drugs with low average Medicare Part B total allowed charges (i.e., less than $100 in 2023).
3. Qualifying biosimilar biological products.

The $100 threshold in 2023 for drugs with low average Medicare Part B total allowed charges is increased each year for inflation by the percentage increase in the CPI-U[15] for the 12-month period ending in June of the previous year. Amounts are rounded to the closest $10.

Special temporary 5-year payment rules for qualifying biosimilar biological products (or qualifying biosimilars) are established by amendments made in section 11403 of the IRA, which is described below. These are biosimilars that, during the temporary 5-year period involved, have an average sales price that is less than the reference biological product.

Information Reported by the Secretary

For each calendar quarter, beginning with the 1st quarter of 2023, the Secretary has six months after the end of the quarter to report to manufacturers the rebate amount that the manufacturer must pay for Part B rebatable drugs furnished during the quarter with price increases above the rate of inflation. The information reported to the manufacturer must also include the total number of units and billing codes for the drug and calendar quarter, and the amount by which the payment rate for the drug furnished during that quarter exceeded the rate of inflation. The total number of units excludes 340B units and packaged units (i.e., units packaged into payment for an item or service that are not separately payable).

For calendar quarters in 2023 and 2024, the Secretary may delay reports to manufacturers for those calendar quarters until September 30, 2025.

[15] The consumer price index for all urban consumers (United States city average).

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Rebate Payment

Upon receipt of a report from the Secretary for a calendar quarter, the manufacturer must pay a rebate based on the difference between the growth in the average sales price (ASP) and CPI-U for its Part B rebatable drugs furnished to Medicare beneficiaries during that quarter. Specifically, the rebate payment amount is calculated as the product of the following:

- The total number of Medicare Part B units of the drug in the relevant quarter (other than 340B units and packaged units); and
- The amount which the payment rate for the drug during the quarter exceeds the inflation-adjusted payment amount.

The inflation-adjusted payment amount for a quarter is equal to the payment amount for the drug in the 3rd quarter of 2021 (referred to as the payment amount benchmark quarter) increased by the percentage growth, if any, between the rebate period CPI-U and the benchmark period CPI-U. The benchmark period CPI-U is the CPI-U for January 1, 2021. The rebate period CPI-U is the greater of:

- The benchmark period CPI-U; and
- The CPI-U for the first month of the calendar quarter that is two calendar quarters before the calendar quarter involved.

The Secretary must either reduce or waive entirely the rebate amount for a calendar quarter for a Part B rebatable drug that is either a drug on the FDA's drug shortage list at any point during that quarter or a biosimilar with respect to which the Secretary determines there is a severe supply chain disruption during the quarter.

Special Rules for Certain Drugs

For Part B rebatable drugs that are first approved or licensed after December 1, 2020, to determine whether a rebate is owed by a manufacturer for a calendar quarter, the payment amount benchmark quarter will be the 3rd full calendar quarter after the first day on which the drug is first marketed, and the benchmark period CPI-U will be the CPI-U for the first month of the first full calendar quarter after the first day on which the drug is first marketed. Manufacturer rebates for these new drugs would apply as of the later of January 1, 2023 or the sixth full calendar quarter after the first day on which the drug is first marketed.

Selected drugs under the Drug Price Negotiation Program are not subject to the rebate program during the price applicability period for that selected drug. Once the price applicability period for a selected drug terminates, it becomes subject to the mandatory rebate program. To determine whether a rebate is owed by a manufacturer for a calendar quarter after the end of the Drug Price Negotiation Program's price applicability period, the payment amount benchmark quarter will be the 1st calendar quarter of the last year of the price applicability period, and the benchmark period CPI-U will be the CPI-U for July of the year preceding the last year of the price applicability period.

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Beneficiary Coinsurance

Beginning April 1, 2023, beneficiary coinsurance for a Part B rebatable drug that is subject to a rebate is capped at 20 percent of the inflation-adjusted benchmark quarter Part B payment amount. Conforming amendments are made to the ambulatory surgery center payment system and the hospital outpatient prospective payment system to provide the same beneficiary coinsurance protection for Part B rebatable drugs payable separately under those systems and subject to a rebate under this program.

Other Provisions

Civil Money Penalties CMPs. Each manufacturer that does not pay any required rebate amount for a calendar quarter is subject to CMPs of not less than 125 percent of the rebate amount.

Exclusion from Certain Calculations. Rebate amounts are excluded from the calculation of ASP, Best Price, and average manufacturer price.

Waiver of Administrative or Judicial Review. The statute prohibits administrative or judicial review of the determinations of rebate units, whether a drug is a Part B rebatable drug, the rebate calculations, or the calculation of beneficiary coinsurance.

Rebate Deposits. Rebates are deposited in the Medicare Part B Trust Fund.

Funding. A total of $80 million is made available to CMS in FY 2022 to implement the program, of which $12.5 million is allocated for FY 2022 and $7.5 million is allocated for each of FYs 2023 through 2031. Funds remain available until expended.

Sec. 11102. Medicare Part D Rebate by Manufacturers

This section establishes a mandatory rebate program for all manufacturers of covered Part D drugs if the prices charged by a manufacturer for a covered Part D drug increase at a rate in excess of inflation compared to the first three quarters of 2021. If the average manufacturer price (AMP) for a Part D rebatable drug increases faster than the CPI-U, the manufacturer must pay a rebate based on the difference between the AMP and CPI-U. This rebate program is similar to the Part B rebate program in structure; differences include the drugs subject to the rebate program (all covered Part D drugs other than low-cost drugs are subject to rebates), the periods used to compare drug prices (a 12-month period beginning in October of a year) and to determine rebates, the periodicity of rebate payments (annual), the deadline for the first report to manufacturers, and the absence of any specific rule for beneficiary cost-sharing for covered Part D drugs subject to a Part D rebate.

Part D Rebatable Drugs

A Part D rebatable drug is any covered Part D drug with one exception—a drug or biological with an average total Part D cost of less than $100 per individual who uses the drug during the 12-month period beginning on October 1, 2022 (referred to as an applicable period). The $100

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threshold is increased for each subsequent applicable period for inflation by the percentage increase in the CPI-U for the 12-month period beginning with October of the previous applicable period. Amounts are rounded to the closest $10.

Information Reported by the Secretary

For each applicable period (i.e., a 12-month period beginning in October), beginning with the applicable period starting in 2022, the Secretary has 9 months after the end of the period to report to manufacturers the amount of the price that exceeded the rate of inflation for Part D rebatable drugs during that period and the rebate amount that the manufacturer must pay for those drugs.

For the two applicable periods beginning on October 1, 2022 and October 1, 2023, the Secretary may delay reports to manufacturers for those calendar quarters until December 31, 2025.

Rebate Payment

Upon receipt of a report from the Secretary for an applicable period, the manufacturer must pay a rebate based on the difference between the AMP (as defined under the Medicaid drug rebate program) and inflation-adjusted payment amount for each dosage form and strength of its Part D rebatable drugs furnished during that applicable period. Specifically, the rebate payment amount is calculated as the product of the following:

- The total number of units of the Part D rebatable drug in the appliable period (other than 340B units) for each dosage form and strength; and
- The amount which the AMP paid for the dosage form and strength for the drug during that period exceeds the inflation-adjusted payment amount.

A unit is defined as the lowest dispensable amount of the part D rebatable drug as reported under the Medicaid drug rebate program. The exclusion of 340B units applies for plan years beginning in 2026 and thereafter.

Using information required to be reported under the Medicaid drug rebate program, the Secretary determines the volume-weighted average AMP for each dosage form and strength of a Part D rebatable drug and applicable period. The Secretary also calculates the benchmark period manufacturer price, which is the volume-weighted average AMP for each dosage form and strength of a Part D rebatable drug for the first three quarters of 2021 (referred to as the payment amount benchmark period).

The inflation-adjusted payment amount for an applicable period for a dosage form and strength for a Part D rebatable drug is equal to benchmark period manufacturer price for each dosage form and strength for the drug increased by the percentage by which the CPI-U for the first month of the applicable period involved (referred to as the applicable period CPI-U) exceeds the CPI-U for January 2021 (referred to as the benchmark period CPI-U).

The Secretary must either reduce or waive entirely the rebate amount for an applicable period for a Part D rebatable drug under the following circumstances:

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- A brand drug is placed on the FDA's drug shortage list at any point during that period.
- A generic drug or biosimilar for which the Secretary determines there is a severe supply chain disruption during the applicable period.
- A generic drug that the Secretary determines would be placed on the FDA's drug shortage list at any point during the subsequent period absent a reduction or waiver.

Special Rules for Certain Drugs

For Part D rebatable drugs that are first approved or licensed after October 1, 2021, to determine whether a rebate is owed by a manufacturer for an applicable period, the payment amount benchmark period will be the first calendar year after the day on which the drug is first marketed, and the benchmark period CPI-U will be the CPI-U for January of the first year that begins after the date on which the drug is first marketed. In the case of a new formulation (or line extension) of a Part D rebatable drug, the Secretary must establish a formula consistent with the formula used under the Medicaid drug rebate program to determine rebates for these new formulations. A new formulation includes an extended-release formulation, but excludes an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended-release formulation.

Selected drugs under the Drug Price Negotiation Program are not subject to the rebate program during the price applicability period for that selected drug. Once the price applicability period for a selected drug terminates, it becomes subject to the mandatory rebate program. To determine whether a rebate is owed by a manufacturer for an applicable period under the Part D rebate program after the end of the price applicability period under the Drug Price Negotiation Program, the payment amount benchmark period will be the last year of the price applicability period, and the benchmark period CPI-U will be the CPI-U January of the last year of the price applicability period for the selected drug.

Reconciliation

The Secretary must establish a process to reconcile amounts paid as rebates by a manufacturer for a Part D rebatable drug and applicable period where a PDP or MA-PD sponsor revises a report to the Secretary on the number of units dispensed of that covered Part D drug during the applicable period. Underpayments of rebates must be made no later than 30 days after the receipt of the reconciliation notice. The statute is silent on the issue of timing for overpayments.

Other Provisions

Civil Money Penalties CMPs. Each manufacturer that does not pay any required rebate amount for an applicable period is subject to CMPs of not less than 125 percent of the rebate amount.

Information. The Secretary will use information reported by manufacturers and states under the Medicaid drug rebate program as well as data submitted by sponsors of PDP and MA-PD plans.

Exclusion from Certain Calculations. Rebate amounts are excluded from the calculation of ASP, Best Price, and average manufacturer price.

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Waiver of Administrative or Judicial Review. The statute prohibits administrative or judicial review of the determinations of units, whether a drug is a Part D rebatable drug, or the calculation of rebates.

Rebate Deposits. Rebates are deposited in the Prescription Drug Account of the Medicare Part B Trust Fund.

Implementation. For 2022, 2023 and 2024, the Secretary is to implement the program using program instructions or other guidance.

Funding. A total of $80 million is made available to CMS in FY 2022 to implement the Part D rebate program, of which $12.5 million is allocated for FY 2022 and $7.5 million is allocated for each of FYs 2023 through 2031. Funds remain available until expended.

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PART 3—PART D IMPROVEMENTS AND MAXIMUM OUT-OF-POCKET CAP FOR MEDICARE BENEFICIARIES

Sec. 11201. Medicare Part D Benefit Redesign

The following table shows the Part D benefit under current law and as modified by the IRA:

	Current Law	2024 under IRA	2025 under IRA
Deductible			
Beneficiary	Amount based on last year's amount increased by drug spending growth ($480 in 2022)	No change (Amount updated for drug spending growth)	
Initial Benefit Phase: Above the Deductible up to the Initial Coverage Limit			
Initial Benefit Phase	Above $480 deductible up to $4,430 initial coverage limit (in 2022)	No change (amounts updated for spending growth)	Above deductible up to $2,000 annual out-of-pocket threshold
Beneficiary	25%	25%	25%
Plan	75%	75%	65%
Manufacturer	0	0	10% discount (brand)*
Federal Government	0	0	10% subsidy (brand)**
Coverage Gap Above the Initial Coverage Limit up to the Out-Of-Pocket Threshold			
Coverage gap	Above $4,430 up to $10,012*** (in 2022)	No change (amounts updated for spending growth)	Eliminated
Beneficiary	25%	25%	
Plan	75% (generic) 5% (brand)	75% (generic) 5% (brand)	
Manufacturer	70% (brand)	70% (brand)	
Federal Government	0	0	
Catastrophic Range Above the annual out-of-pocket threshold			
Annual Out-of-pocket threshold	$10,012*** (in 2022). Increased by drug spending growth for subsequent years	No change (amount updated for drug spending growth)	$2,000. Increased by drug spending growth for subsequent years
Beneficiary	5%	0	0
Plan	15%	20%	60%
Manufacturer Discount	0	0	20% discount (brand)*
Federal Government Reinsurance	80%	80%	20% (brand) 40% (generic)
Base Beneficiary Premium			
Beneficiary	25.5% of national average monthly bid	Premium growth is capped at 6%	

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Eliminating the Initial Coverage Limit

Beginning in 2025, the IRA replaces the initial coverage limit—or the upper threshold of the initial benefit phase—with the out-of-pocket limit. Before the IRA, the initial benefit phase begins once a beneficiary has paid the deductible and ends once a beneficiary has incurred costs equal the initial coverage limit. That amount, equal to $4,430 for 2022, is set by increasing the prior year's initial coverage limit by a measure of drug price spending growth.

In 2025, the IRA sets the out-of-pocket limit at $2,000. This eliminates the coverage gap and lowers the out-of-pocket limit for the catastrophic phase of the benefit. For 2026 and thereafter, the upper threshold of the initial benefit phase will be calculated by increasing the prior year's amount by the same measure of covered part D drug price spending growth as under present law.

Changes in the Catastrophic Range

Beginning in 2024, beneficiary co-insurance in the catastrophic range is eliminated. (It is equal to 5 percent under current law.)

Beginning in 2025, in combination with reducing the out-of-pocket limit for the catastrophic phase of the benefit, the IRA establishes a cap on copayments for Part D and MA-PD beneficiaries. As noted above, that amount is set at $2,000 for 2025. For 2026 and thereafter, the upper threshold of the initial benefit phase is the prior year's amount increased by the same measure of drug price spending growth as under present law.

Elimination of Coverage Gap

Under the IRA, the coverage gap is eliminated starting in 2025. Because the IRA changes the initial benefit phase to end at $2,000 for 2025 (or, for subsequent years, the prior year's amount increased by drug price spending growth) and the catastrophic phase begins at that same figure, there is no longer any coverage gap. The coverage gap provisions of the statute sunset as of January 1, 2025.

Reinsurance

Under existing law, Medicare subsidizes 80 percent of total drug spending incurred by Part D enrollees with drug spending above the catastrophic coverage threshold. Under the IRA, starting in 2025, Medicare will subsidize an amount equal to the sum of 20 percent of the costs of *applicable drugs* incurred after an individual has exceeded the annual out-of-pocket threshold plus 40 percent of the costs incurred after an individual has exceeded the annual out-of-pocket threshold of the costs of *non-applicable drugs*.

- Applicable drugs are defined as those approved under new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act or a biologic licensed under section 351 of the PHSA and are included on a Part D or MA-PD plan formulary (or, if the sponsor does not use a formulary, then drugs for which benefits are available under the plan) as well as those covered through an exception or appeal. Effectively these are brand name drugs that are not subject to the Drug Price Negotiation Program summarized above.
- Non-applicable drugs are those selected drugs under the Drug Price Negotiation Program summarized above.

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New Manufacturer Discount Program

Beginning on January 1, 2025, new section 1860D-14C establishes a manufacturer discount program for Part D enrollees who have incurred costs in excess of the annual deductible and who are not enrolled in a qualified retiree prescription drug plan. The discount program applies to brand name drugs (those originally approved under a new drug application or a biologic licensed under section 351 of the PHSA) that are on the formulary of the sponsor, or if there is no formulary, drugs for which coverage is provided, as well as those drugs covered through an exception or appeal. It does not apply to those drugs selected for negotiation under the Drug Price Negotiation Program summarized above.

Discount Agreements. Under the program, manufacturers enter into an agreement with the Secretary to provide discounts for these drugs dispensed to Part D beneficiaries. For plan year 2025, the agreement must be entered into by March 1, 2024. For subsequent plan years, the Secretary will set the deadline, which may be on a quarterly or semi-annual basis. Agreements are not less than 12 months in length and are renewed automatically unless terminated by one of the parties. The Secretary may terminate an agreement for willful violations of its requirements or other good cause. If requested, the Secretary must provide for a hearing to review such terminations. A manufacturer terminating an agreement must do so before January 31 for the succeeding plan year. If it terminates after January 31, it can only terminate for the second succeeding plan year.

General Rule for Discounts. Unless a manufacturer qualifies for a phased-in discount as described below, manufacturers must provide a discounted price, beginning in 2025, equal to:

- 90 percent of the negotiated price for those beneficiaries who have not yet exceeded their annual out-of-pocket threshold; and
- 80 percent of the negotiated price for those beneficiaries who have exceeded the annual out-of-pocket threshold.

Discounts provided under the Manufacturer Discount Program do not impact the liability of a beneficiary for any required copayments or coinsurance, nor the ability of a beneficiary to purchase a covered drug that is not an applicable drug or a drug that is not on the formulary of their plan.

Phased-In Discounts for LIS Beneficiaries. For certain manufacturers and with respect to drugs provided to LIS beneficiaries, the discounts would be phased in such that manufacturers would be required to provide a discounted price—determined by multiplying the negotiated price by the applicable percentage for the year involved, shown in the following schedule:

	For those LIS beneficiaries who have not yet exceeded their annual out-of-pocket threshold	For those LIS beneficiaries who have exceeded their annual out-of-pocket threshold
2025	99 percent	99 percent
2026	98 percent	98 percent
2027	95 percent	95 percent
2028	92 percent	92 percent
2029	90 percent	90 percent

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2030	(For 2029 and thereafter)	85 percent
2031		80 percent (For 2031 and thereafter)

Manufacturers permitted to phase in discounts applicable to LIS beneficiaries are those that had a coverage gap discount agreement under section 1860D-14A in effect in 2021 and for which:

- Total spending for all of the Part D drugs of the manufacturer covered by that agreement was less than 1 percent of the total Part D spending during 2021; and
- Total spending for all of the drugs of the manufacturer that are single source drugs and biological products covered under Part B during 2021 was less than 1 percent of the total Part B spending for all drugs or biological products covered during 2021.

Phased-In Discounts for "Specified Small Manufacturers." The same phase-in schedule established for drugs for LIS beneficiaries also applies to certain "Specified Small Manufacturers." These are manufacturers that have a coverage gap discount agreement under section 1860D-14A in effect in 2021 and that have total spending under Part D for any one of their drugs covered by the coverage gap discount agreement equal to more than 80 percent of the total Part D spending for all drugs of that manufacturer.

Both phase-in schedules apply to drugs of qualifying manufacturers that are produced, prepared, propagated, compounded, converted, or processed by the manufacturer. All persons treated as a single employer under the Internal Revenue Code are considered to be a single manufacturer for this purpose. A manufacturer acquired by another manufacturer that is not a Specified Small Manufacturer is not included as a Specified Small Manufacturer for the purpose of applicability of the phased-in discount schedule.

Total spending with respect to Part D for the purpose of determining eligibility for phase-in discounts includes ingredient costs, dispensing fees, sales tax, and if applicable, vaccine administration fees. Total spending with respect to Part B for the purpose of determining eligibility for phase-in discounts excludes spending for a drug or biological that is bundled or packed into payment for another service.

Discounts for Claims that Cross Phases of the Part D Benefit. When the negotiated price of a claim for an applicable drug that is subject to a discount under the Manufacturer Discount Program falls only in part above the annual deductible, the manufacturer provides the discounted price on only the portion of the negotiated price that falls above the deductible. Likewise, where the amount of the negotiated price of an individual claim for the drug falls in part above and in part below the annual out-of-pocket threshold, the manufacturer provides the 10 percent discount applicable to the portion of the claim below the annual out-of-pocket threshold plus the 20 percent discount applicable to the portion of the claim that falls above that threshold.

Administering Discounts. The Secretary will establish policies to (i) determine the discounted prices for applicable drugs; (ii) establish procedures to ensure that a pharmacy or mail order service is reimbursed for the negotiated price less the discount within 14 days for electronic claims and 30 days for other claims; (iii) ensure that discounts are provided before other coverage or financial assistance is applied; and (iv) establish a dispute mechanism to resolve

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disagreements between manufacturers, beneficiaries and a third-party contractor administering the program on behalf of the Secretary. The Secretary must also monitor compliance with the discount program and may collect appropriate data from Part D and MA-PD plans for the purposes of providing discounted prices.

The Secretary may not receive or distribute funds of a manufacturer in administering the program.

Manufacturer Duties and Enforcement. Manufacturers must collect and have available such data as the Secretary determines is needed to demonstrate compliance with the agreements. Unlike the Build Back Better Act (BBBA) as passed by the House of Representatives in 2021, the IRA does not specify that manufacturers must subject to periodic audits by the Secretary. However, the IRA does subject manufacturers to civil money penalties of 125 percent of the amount of the discounts for failure to provide the discounted prices.

The provision includes several definitions:

- *Manufacturer*. A manufacturer under this section is defined as an entity engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly. Such term does not include a wholesale distributor of such drugs or a retail pharmacy licensed under state law.
- *Negotiated Price*. Refers to the definition of negotiated price in 42 CFR 423.100 (existing Part D regulations) and would include any dispensing fee and vaccine administration fee, if applicable.

Discounted prices under this section will be incorporated in the actuarial valuation of Part D bids.

New Selected Drug Subsidy Program

New section 1860D-14D requires the federal government to provide plan sponsors a 10 percent subsidy toward the negotiated price for those covered Part D drugs selected for negotiation under the new Drug Price Negotiation Program dispensed to Part D and MA-PD enrollees who have incurred costs above the deductible but below the annual out-of-pocket threshold.

Stabilizing the Beneficiary Premium

Under current law, a beneficiary is required to contribute 25.5 percent toward the premium cost of standard drug coverage under Part D. Under the BBBA, the premium percentage would have been reduced to 23.5 percent beginning in 2024.

The IRA adopts a different policy. For each of the 2024 through 2029 plan years, it caps the amount by which the monthly base premium may grow by 6 percent. For each of those plan years, the base beneficiary premium for a month will be the lesser of (i) the base beneficiary premium for the previous year increased by 6 percent or (ii) the base beneficiary premium that would be calculated if the 6 percent cap is not applied. The 6 percent cap does not apply in 2030 and subsequent years.

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However, starting with the 2030 plan year, the beneficiary premium contribution toward standard drug coverage of 25.5 percent shall be modified by the Secretary by whatever percentage point adjustment is necessary to ensure that the base beneficiary premium for a month in 2030 is equal to the lesser of the following:

- 106 percent of the base beneficiary premium for a month in 2029; or
- The base beneficiary premium calculated for a month in 2030 using the 25.5 percent beneficiary contribution under existing law.

In no case may the beneficiary contribution be less than 20 percent.

Waiver of Rulemaking Requirements

Requirements for rulemaking to carry out the many provisions of this section during 2024, 2025 and 2026 are waived; they may be implemented through program instruction or otherwise.

Implementation Funding

The IRA provides funding to CMS to implement the Part D Benefit Redesign provisions as follows:

- For fiscal year (FY) 2022, $341 million, including $20 million for FY 2022 and $65 million for FY 2023; and
- For each of FYs 2024 through 2031, $32 million.

Funds remain available until expended.

Sec. 11202. Maximum Monthly Cap on Cost Sharing Payments Under Prescription Drug Plans and MA-PD Plans.

For plan years beginning on or after January 1, 2025, PDPs and MA-PD plan sponsors must permit an enrollee, including an LIS enrollee, to opt to spread their payments for certain cost sharing amounts over a period of time as described below. A beneficiary may make an election prior to a plan year or in any month during the plan year.

If the beneficiary elects to spread out their cost-sharing, the plan sponsor bills the beneficiary a monthly amount which is subject to a ceiling. The ceiling for a month is calculated as follows:

- For the first month after the election, the annual out-of-pocket threshold ($2,000 in 2025) minus the incurred costs divided by the number of months remaining in the plan year;
- For each subsequent month, the sum of any remaining out-of-pocket costs owed divided by the number of months remaining in the plan year.

Examples of Maximum Monthly Cap on Cost Sharing Payments with 6 Months Remaining in the Plan Year

	Beneficiary A incurs $1,800 in out-of-pocket costs*	**Beneficiary B incurs $800 in out-of-pocket costs***
Month 1	($2,000 - $1,800)/6 =$33.33	($2,000 - $800)/6 =$200
Month 2	($1,800-$33.33) or $1,767/5	($800-$200)/5 or $600/5

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	$353	$120
Month 3	1767-353/4 or 1414/4 $353	($600-$120)/4 or $480/4 $120
Month 4	1414-354/3 or 1060/3 $353	($480-$120)/3 or $360/2 $120
Month 5	1060-353/2 or 707/2 $353	($360-$120)/2 or $240/2 $120
Month 6	$353	$120

*Figures are rounded and may not sum to totals because of rounding.

The Secretary of HHS must provide information to Part D eligible individuals regarding the option. PDP and MA-PD sponsors must:

- Notify prospective enrollees, prior to the start of the plan year, regarding the option and include information on the option in educational materials;
- Have a mechanism in place to notify a pharmacy during a plan year when an enrollee incurs out-of-pocket costs that the enrollee may benefit from the election;
- Provide that the pharmacy informs the beneficiary of such option after it receives such a notification;
- Ensure that an election under this option does not impact payments (or the timing of payments) to a pharmacy; and
- Have a financial reconciliation process to correct inaccuracies in payments made by an enrollee electing the option.

PDP and MA-PD sponsors may not limit the option for an enrollee to make such an election to certain covered part D drugs.

An election under this provision will be terminated if an enrollee fails to pay the billed monthly amounts, and the PDP sponsor or MA organization may preclude the enrollee from making such an election in a subsequent plan year.

Nothing under this provision prevents a PDP or MA-PD sponsor from billing enrollees for past due amounts. Unsettled balances of amounts owed under this provision are treated as plan losses; the Secretary is not liable for those amounts outside of those assumed as losses estimated in plan bids.

This section waives requirements for rulemaking to carry out provisions during 2025; they may be implemented through program instruction or otherwise.
Funding for CMS to carry out this section is provided: $10 million is made available to CMS for FY 2023, which remains available until expended.

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PART 4—CONTINUED DELAY OF IMPLEMENTATION OF PRESCRIPTION DRUG REBATE RULE

Sec. 11301. Extension of Moratorium of Implementation of Rule Relating to Eliminating the Anti-Kickback Statute Safe Harbor Protection for Prescription Drug Rebates.

On November 30, 2020, the HHS Office of the Inspector General (OIG) published a final rule titled, "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees" (87 FR 76666). Section 11301 of the IRA prohibits the Secretary from implementing, administering or enforcing the provisions of that rule prior to January 1, 2032.

The rule eliminated safe harbor protections for drug rebates negotiated by pharmacy benefit managers (PBMs) in order to offer those protections to discounts provided directly to consumers. Specifically, the rule amended the safe harbor that protects from federal anti-kickback requirements certain price discounts provided to individuals and entities, including health care providers, who solicit or receive price reductions, and the individuals and entities who offer to pay them. The final rule eliminated from that safe harbor the rebates provided from a manufacturer to a Part D plan sponsor (including a Medicare Advantage plan offering drug coverage). The rule also established two new safe harbors. One protects discounts provided by manufacturers to Part D plan sponsors and Medicaid managed care plans if they are given at point-of-sale. The second protects flat fee service payments that manufacturers make to PBMs for specific activities.

Judicial, administrative and congressional action pushed back the rule's implementation multiple times—for example, until January 1, 2026, in the Infrastructure Investment and Jobs Act,[16] and until January 1, 2027, in the Bipartisan Safer Communities Act.[17] This section of the IRA prohibits implementation before January 1, 2032, a 5-year extension.

[16] P.L. 117-58, enacted November 15, 2021
[17] P.L. 117-159, enacted June 25, 2022

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PART 5—MISCELLANEOUS

Sec. 11401. Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices Under Medicare Part D.

For coverage beginning January 1, 2023, PDPs and MA-PDs may not charge any cost sharing for adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC).

Because PDPs and MA-PDs submitted their 2023 bids prior to the enactment of this provision (and thus those bids did not account for these costs), the IRA provides a temporary retrospective subsidy to PDPs and MA-PDs to cover these costs for 2023. The Secretary is required to provide this subsidy for the aggregate reduction in cost sharing and deductibles for 2023 by no later than 18 months following the end of the applicable plan year (i.e., by June 30, 2025).

Section 11401(d) states that this provision does not limit coverage under Part D for vaccines that are *not* recommended by ACIP. Section 11401(e) states that the Secretary shall implement this section—including amendments made by this section for 2023, 2024, and 2025—by program instruction or other forms of program guidance.

Sec. 11402. Payment for Biosimilar Biological Products During Initial Period.

Section 1847A of the Social Security Act specifies the calculation for payments of drugs and biologics under Medicare Part B using a methodology generally relying on average sales price (ASP). For biosimilars, the Part B payment is generally the biosimilar's ASP plus 6 percent of the reference product's ASP. However, in cases where ASP is not available during the first quarter of sales for the new biosimilar, CMS has been using 103 percent of wholesale acquisition cost (WAC).

Under this section of the IRA, on or after July 1, 2024, where ASP is not available during the first quarter of sales for the new biosimilar, the Part B payment will be the lesser of the price Medicare pays for the biosimilar's reference product or 103 percent of the biosimilar's WAC.

Sec. 11403. Temporary Increase in Medicare Part B Payment for Certain Biosimilar Biological Products.

For biosimilars, the Part B payment is generally the biosimilar's ASP plus 6 percent of the reference product's ASP. This section of the IRA increases the percentage to 8 percent for the applicable 5-year period for qualifying biosimilars.

Applicable 5-year period means:

- For a biosimilar for which Part B payments were made as of September 30, 2022, the 5-year period beginning October 1, 2022; and

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- For a biosimilar for which Part B payments were made after September 30, 2022, the 5-year period beginning on the first day of the quarter during which a Part B payment is first made.

Qualifying biosimilar biological product means a biosimilar with an ASP lower than that of the reference biological product, determined on a quarterly basis during the applicable 5-year period. Thus, the biosimilar would not qualify for the 2 percentage point increase for any quarter during the applicable 5-year period in which the biosimilar's ASP exceeds that of the reference product.

Sec. 11404. Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program.

Under current law, the Part D low-income subsidy (LIS) program provides assistance with the costs of Part D premiums and cost-sharing (including deductibles) to Part D enrollees with incomes up to 150 percent of the federal poverty level (FPL). However, the degree of assistance varies based on income. Part D enrollees with incomes up to 135 percent of the FPL and lower resources receive full LIS benefits whereas those with income between 135-150 percent of the FPL and higher resources receive partial benefits.

Beginning with plan year 2024, full LIS benefits will be available to Part D enrollees with income between 135-150 percent of the FPL and higher resources, and the partial LIS benefit will be eliminated.

Sec. 11405. Improving Access to Adult Vaccines Under Medicaid and CHIP.

This section adds a mandatory Medicaid benefit with no cost sharing for approved adult vaccines (and their administration) recommended by ACIP. This mandatory benefit is also added to the State Children's Health Insurance Program (CHIP) for individuals age 19 or older.[18]

The Medicaid and CHIP changes made by this section will take effect on October 1, 2023.

Since 2013, such vaccines were an optional Medicaid benefit for which states could obtain a 1 percentage point increase in their federal Medicaid matching rate—that is, the federal medical assistance percentage (FMAP). States that had implemented this optional Medicaid benefit with no cost sharing as of August 16, 2022, will continue to receive the 1 percent FMAP increase for another 8 fiscal quarters once the mandatory requirement begins (i.e., October 1, 2023, through September 30, 2025). Otherwise, the state's regular FMAP applies.

[18] Adults age 19 and older may be eligible for CHIP-funded coverage in a state covering pregnant women under either the state plan option for targeted low-income pregnant women (§2112) or through continuation of an existing 1115 waiver.

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Sec. 11406. Appropriate Cost-Sharing for Covered Insulin Products Under Medicare Part D.

Insulin and related supplies are covered under Part D with the exception of insulin that is administered through an infusion or inhalation pump, which is covered under Part B. Insulin covered under Part D is subject to the Part D deductible and applicable cost-sharing.

Starting with the 2023 plan year and for subsequent plan years, the deductible is waived for covered insulin products under Part D.

Also starting in 2023 and for succeeding years, cost-sharing for Part D covered insulin products will be capped. This will apply notwithstanding the Part D benefit redesign summarized in Part 3 above. For plan years 2023, 2024, and 2025, the monthly cost-sharing that may be charged to Part D enrollees for covered insulin products is capped at $35. For plan years beginning after 2025, the monthly cost-sharing will be capped at the lowest of the following:

- $35;
- 25 percent of the maximum fair price under the Drug Price Negotiation Program; or
- 25 percent of the negotiated price under the PDP or MA-PD plan.

For the first three months of 2023, the PDP or MA-PD plan must reimburse a Part D enrollee for monthly cost-sharing charged in excess of $35 for the month's supply at the point of sale. The cost-sharing caps also apply under the LIS benefits program.

The federal government will provide a temporary, retrospective subsidy to plans for 2023 to offset aggregate reductions in cost-sharing and deductibles by reason of these changes. The subsidy payment will be made no later than 18 months after the end of the plan year (i.e., by June 30, 2025).

Implementation for plan years 2023, 2024, and 2025 will be done by program instruction or other program guidance. For fiscal year 2022, $1.5 million is appropriated to carry out the policy, which remains available until expended.

Sec. 11407. Limitation on Monthly Coinsurance and Adjustments to Supplier Payment Under Medicare Part B for Insulin Furnished Through Durable Medical Equipment.

As noted in the previous section, insulin that is administered through an item of durable medical equipment (i.e., an infusion or inhalation pump) is covered under Part B. This insulin is subject to applicable cost-sharing, namely the deductible and a 20 percent coinsurance of the payment amount determined using the average sales price methodology.

Starting in July 2023, no deductible will apply to the costs of insulin furnished through covered durable medical equipment, and the beneficiary will not be required to pay more than $35 for a month's supply of that insulin.

Payment amounts that would otherwise be made to suppliers will be adjusted to reflect the $35 monthly cap on beneficiary cost-sharing.

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Implementation for 2023 will be done by program instruction or other program guidance.

Sec. 11408. Safe Harbor for Absence of Deductible for Insulin.

Section 223 of the Internal Revenue Code of 1986 permits an income tax deduction for contributions to a health savings account with respect to high deductible health plans. The definition of high deductible health plan is amended to ensure that not applying the deductible with respect to insulin under the plan will not disqualify the plan from being treated as a high deductible health plan. This rule (referred to as a safe harbor) is similar to the special treatment for the nonapplication of the deductible for preventive care or for health care services furnished through telehealth or other remote care during the COVID-19 public health emergency under high deductible health plans.

Insulin is defined as any dosage form (such as vial, pump, or inhaler dosage forms) of any different type (such as rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-acting, and premixed) of insulin.

The safe harbor applies for plan year 2023 and each subsequent plan year.

Subtitle C—Affordable Care Act Subsidies

Sec. 12001. Improve Affordability and Reduce Premium Cost of Health Insurance for Consumers.

The American Rescue Plan Act of 2021 (ARP, P.L. 117-2) was signed into law on March 11, 2021, and temporarily increased the premium assistance for individuals purchasing health insurance coverage through health insurance Exchanges for taxable years 2021 and 2022:

- The amount of premium tax credit was increased for individuals with income below 400 percent of the federal poverty level (FPL).
    - For example, those with income between 300 and 400 percent FPL qualify for premium subsidies that limit their premiums to between 6 and 8.5 percent of income (respectively) for the second lowest cost silver metal-level plan available in their area, rather than 9 percent of income.
    - Those with income below 150 percent FPL qualify for premium subsidies that cover the full amount of the second lowest cost silver metal-level plan available in their area, rather than between 2 percent and 3 percent of income, depending on their income.
- Premium tax credits were made available for the first time for individuals with income above 400 percent FPL—to the extent that their health insurance premium for the second lowest cost silver metal-level plan exceeds 8.5 percent of their income. Previously premium tax credits were not available for individuals with income above 400 percent FPL.

The IRA extends these ARP premium-subsidy provisions (Figure 1) for 3 additional years, through tax year 2025.

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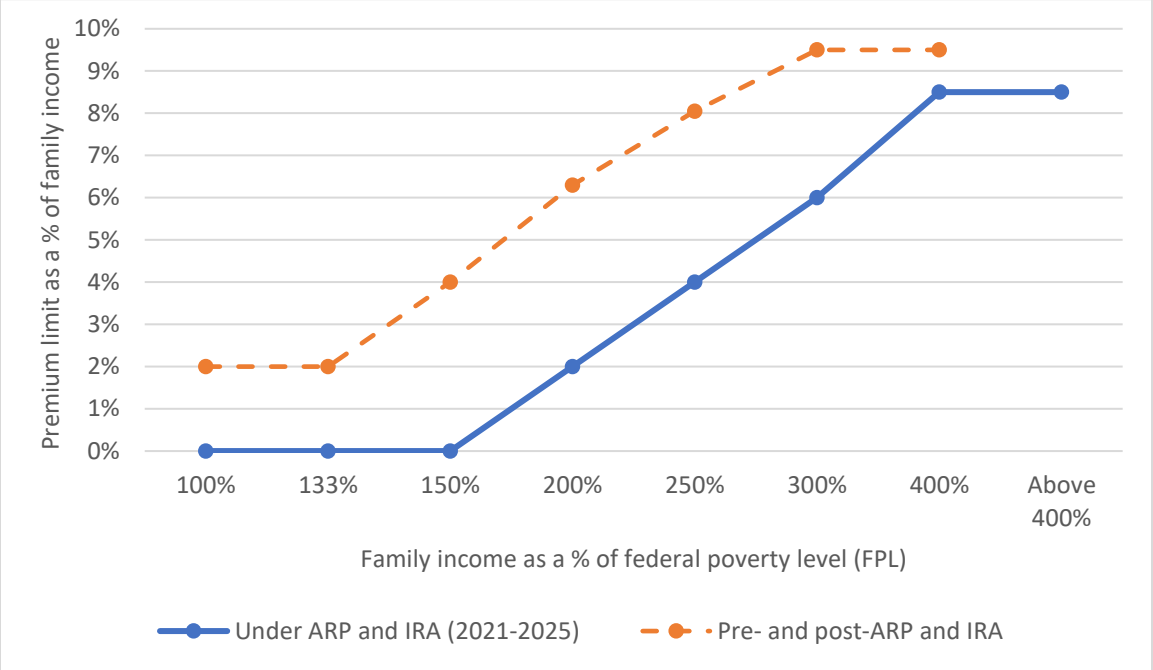
Figure 1. Maximum out-of-pocket premium payment for second lowest cost silver plan in a health insurance Exchange, by family income as percentage of federal poverty level (FPL)



Source: HPA analysis of 36B of the Internal Revenue Code, including as amended by the American Rescue Plan Act of 2021 (ARP) and the Inflation Reduction Act of 2022 (IRA).
Note: In the 48 contiguous states in 2022, 100% FPL is $13,590 for an individual and $4,720 for each additional person.

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Physician Fee Schedule Proposed Rule for 2023
Summary Part II

Medicare and Medicaid Program: 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

[CMS-1770-P]

On July 7, 2022, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule relating to the Medicare physician fee schedule (PFS) for CY 2023[1] and other revisions to Medicare Part B policies. The proposed rule is scheduled to be published in the July 29, 2022 issue of the *Federal Register*. If finalized, policies in the proposed rule generally would take effect on January 1, 2023. **The 60-day comment period ends at close of business on September 6, 2022.**

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

Part II includes proposals related to the Medicare Shared Savings Program. These are designed to strengthen financial incentives for long-term participation by modifying the benchmarking methodology, expanding opportunities for certain low revenue ACOs and those serving high risk and dual eligible populations. It also aims to make operational improvements to reduce administrative burden and makes numerous revisions to the quality reporting and the quality performance requirements.

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[1] Henceforth in this document, a year is a calendar year unless otherwise indicated.

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1. Executive Summary

Under the Shared Savings Program, providers and suppliers that participate in an Accountable Care Organization (ACO) continue to receive traditional Medicare 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, 2022, over 11 million people with Medicare receive care from one of the 528,966 health care providers in the 483 ACOs participating in the Shared Savings Program.

CMS says policies in this proposed rule are intended to reverse the following recent trends in the Shared Savings Program and to **advance equity** (CMS' emphasis):

- In recent years, growth in the number of beneficiaries assigned to ACOs has plateaued.
- Higher-spending populations are increasingly underrepresented in the program since the change to regionally adjusted benchmarks.
- Access to ACOs appears inequitable as shown by data indicating that Black (or African American), Hispanic, Asian/Pacific Islander, and American Indian/Alaska Native beneficiaries are less likely to be assigned to an ACO than their Non-Hispanic White counterparts.

CMS cites feedback from health care providers treating underserved populations—that they require upfront capital to make the necessary investments to succeed in accountable care and may also need additional time under a one-sided model before transitioning to performance-based risk (also known as a two-sided model). Thus, CMS proposes to provide advance shared savings payments to low revenue ACOs that are inexperienced with performance-based risk Medicare ACO initiatives, that are new to the Shared Savings Program, and that serve underserved populations. These advance investment payments (AIPs) would increase when more beneficiaries who are dually eligible for Medicare and Medicaid or who live in areas with high deprivation (measured by the area deprivation index (ADI)),[4] or both, are assigned to the ACO. These funds—a one-time fixed payment of $250,000 and quarterly payments for the first 2 years of an ACO's 5-year agreement period, remaining available for use over the 5-year period—would be available to address the social needs of people with Medicare, as well as health care provider staffing and infrastructure. CMS says additional proposed modifications would support organizations new to accountable care by providing greater flexibility in the progression to performance-based risk, allowing these organizations more time to redesign their care processes to be successful under risk arrangements.

[2] In this section of the summary, all references to ACOs are to ACOs participating in the Shared Savings Program.
[3] Section 1899 of the Act contains statutory provisions of the Shared Savings Program, with regulations codified at 42 CFR part 425.
[4] The preamble of the proposed rule describes the background of the ADI measure and how it is calculated. The ADI data files are publicly available for download at https://www.neighborhoodatlas.medicine.wisc.edu/.

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CMS is also proposing a health equity adjustment that would upwardly adjust ACOs' quality performance scores to continue encouraging high ACO quality performance, transition ACOs to all-payer electronic clinical quality measures (eCQMs) and Merit-based Incentive Payment System clinical quality measures (MIPS CQMs), and support those ACOs serving a high proportion of underserved beneficiaries while also encouraging all ACOs to treat underserved populations. Finally, CMS is proposing certain changes to the benchmarking methodologies to encourage participation by health care providers who care for populations that include a high percentage of beneficiaries with high clinical risk factors and beneficiaries dually eligible for Medicare and Medicaid.

In this proposed rule, CMS says it is accomplishing the following:

- Strengthening financial incentives for long term participation by reducing the impact of ACOs' performance on their benchmarks;
- Addressing the impact of ACO market penetration on regional expenditures used to adjust and update benchmarks;
- Supporting the business case for ACOs serving high risk and dually eligible populations to participate;
- Modifying the benchmarking methodology to mitigate bias in regional expenditure calculations that benefits ACOs electing prospective assignment;
- Expanding opportunities for certain low revenue ACOs participating in the BASIC track (one-sided shared savings-only model) to share in savings even if they do not meet the minimum savings rate (MSR), to allow for investments in care redesign and quality improvement activities among less capitalized ACOs;
- Eliminating the requirement for an ACO to submit marketing materials to CMS for review and approval prior to disseminating materials to beneficiaries and ACO participants (but still requiring submission of marketing materials to CMS upon request);
- Streamlining the SNF 3-day rule waiver application review process;
- Reducing the frequency with which beneficiary information notices are provided to beneficiaries (from annually to a minimum of once per agreement period, with a proposed follow-up beneficiary communication serving to promote beneficiary comprehension of the standardized written notice);
- Revising data-sharing requirements to recognize ACOs structured as organized health care arrangements (OHCAs) for data sharing purposes; and
- Making numerous revisions to the quality reporting and the quality performance requirements for performance year 2023 and subsequent performance years.

CMS anticipates that the Shared Savings Program proposals will increase participation, particularly from ACOs serving beneficiaries with greater needs and higher baseline spending. The incentive for ACOs to reduce spending over multiple agreement periods is also expected to be bolstered—for example, by reducing the weighting on the regional component of the benchmark update and by providing a prior savings adjustment at rebasing.

CMS projects a $15.5 billion decrease in spending on benefits (that is, savings from efficiency) and $650 million in higher net shared savings payments to ACOs, resulting in $14.8 billion lower overall spending compared to the program baseline.

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To make these changes, CMS cites the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. Specifically, CMS lists the following proposals as requiring use of 1899(i) authority:

- Allowing for AIPs;
- Modifying the calculation of the shared loss rate under the ENHANCED track to allow for a sliding scale based on an alternative quality performance standard;
- Incorporating a prospectively projected administrative growth factor—a variant of the United States Per Capita Cost (USPCC), referred to in this proposed rule as the Accountable Care Prospective Trend (ACPT)—into a three-way blend with national and regional growth rates to update an ACO's historical benchmark and address increasing market saturation by ACOs in a regional service area;
- Expanding the 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 MSR as required under section 1899(d)(1)(B)(i) of the Act; and
- Excluding the proposed new supplemental payment for Indian Health Service (IHS)/Tribal hospitals and Puerto Rico hospitals from the determination of Medicare Parts A and B expenditures used in certain financial calculations under the Shared Savings Program.

These provisions are summarized in greater detail below.

2. Shared Savings Program Participation Options

a. Increasing Participation in Accountable Care Models in Underserved Communities by Providing an Option for Advance Investment Payments to Certain ACOs

CMS lays out the rationale for the new AIPs by describing a need for start-up ACO investment, relying on the experience of prior models that provided such funding. CMS acknowledges that the start-up investment costs for an ACO can be substantial, particularly for a small organization or an organization caring for underserved or more medically complex patients. The CMS Innovation Center previously tested two models to assess whether such up-front payments would increase participation in the Shared Savings Program by ACOs serving rural or underserved regions—the Advance Payment (AP) ACO Model, which operated from 2012 to 2015, and the ACO Investment Model (AIM), which operated from 2015 to 2018. Both models operated by prepaying shared savings to ACOs and later recouping those amounts from earned shared savings (if any).

AP ACOs received between $1.3 million and $2.7 million in prepaid shared savings, via an up-front payment of $250,000 per ACO plus $36 per beneficiary, followed by an $8 per beneficiary per month payment for 2 years. In AIM, the prepaid shared savings amounts were distributed and recouped in the same amounts and manner as the AP ACO model for the majority of model participants. The AP Model did not significantly improve the quality or cost of care. However,

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AIM successfully encouraged ACOs to form in areas where ACOs may not have otherwise formed and where other Medicare payment and delivery innovations were less likely to be present. AIM generated an estimated net aggregate reduction in spending by Medicare of $381.5 million after accounting for Medicare's payment of AIM funds and ACOs' earned shared savings, without reducing the quality of care provided to beneficiaries. CMS acknowledged continued interest in the AIM and AP ACO models and approaches with similar up-front and ongoing payments for ACOs newly participating in the Shared Savings Program.

Consequently, CMS proposes to make advance shared savings payments—referred to as advance investment payments (AIPs)—to certain ACOs participating in the Shared Savings Program, to improve the quality and efficiency of items and services furnished to Medicare beneficiaries. Such payments would be made in accordance to standards proposed in a new 42 CFR §425.630.

CMS envisions that this new payment option would distribute AIPs to ACOs for 2 years in order to reduce the financial barriers encountered by small providers and suppliers as they join the Shared Savings Program. These payments would be recouped from shared savings the ACO earned, if any.

AIP Eligibility. CMS proposes to limit eligibility for AIP funding to new ACOs and ACOs inexperienced with performance-based risk Medicare ACO initiatives. AIP eligibility builds on AIM, but with more inclusive eligibility criteria that CMS considers necessary to scale advance payments from a model to a regular component of the Shared Savings Program and to align with the Innovation Center's stated vision for health care transformation. CMS is also broadening the eligibility criteria compared to AIM to reflect its belief that it is important to provide an incentive for providers and suppliers who serve high need beneficiaries in all areas to form ACOs, including underserved beneficiaries who reside in urban areas. Therefore, CMS does not limit the opportunity for an ACO to receive AIPs to ACOs in only rural communities or in areas with low ACO penetration.

Specifically, in proposed §425.630(b), an ACO would need to meet all of the following criteria to be eligible for AIPs:

- Not a renewing ACO or re-entering ACO;
- Has applied to participate in the Shared Savings Program under any level of the BASIC track glide path (because this participation option is indicative of an ACO's inexperience with performance-based risk, in which ACOs are typically less experienced with risk and are more likely to benefit from up-front funding or ongoing financial assistance);
- Eligible to participate in the Shared Savings Program;
- Inexperienced with performance-based risk Medicare ACO initiatives; and
- A low revenue ACO (defined in current §425.20 as having less than 35 percent of its Medicare A and B fee-for-service revenue through assigned beneficiaries based on the most recent calendar year for which 12 months of data are available).

CMS seeks comments on these proposals.

AIP Application Procedure. The initial application cycle to apply for AIPs would be for a January 1, 2024, start date. In the new §425.630(c), CMS proposes to codify the application

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process for AIPs. In order to obtain a determination regarding whether an ACO may receive AIPs, it must submit, as part of its application to participate in the Shared Savings Program, complete supplemental application information in the form and manner and by a deadline specified by CMS.

The application cycle for AIPs would be conducted as part of and in conjunction with the Shared Savings Program application process, with instructions and timelines published through the Shared Savings Program website. As previously mentioned, ACOs currently participating in the Shared Savings Program or applying to renew their participation agreement would not be eligible to apply. CMS intends to provide further information regarding the process, including the application and specific requirements such as the deadline for submitting applications, through subregulatory guidance and will also provide a feedback process to afford an opportunity for the applicant to clarify or revise its application.

AIP application contents. As proposed in the new §425.630(d), an ACO would be required to submit a spend plan as part of its application for AIPs. The spend plan must:

- Identify how the ACO will spend the AIPs during the agreement period to build care coordination capabilities (including coordination with community-based organizations, as appropriate),
- Address specific health disparities,
- Meet other criteria under §425.630,
- Identify the categories of goods and services that will be purchased with AIPs, the dollar amounts to be spent on the various categories, and such other information as may be specified by CMS, and
- State that the ACO will establish a separate designated account for the deposit and expenditure of all AIPs.

CMS says it does not intend for the proposed spend plan to create a benchmark requirement against which it would hold the ACO accountable, but rather it is intended to aid CMS in tracking ACO progress toward implementing their spend plan and any challenges or changes in strategy that occur following their receipt of AIPs.

Use and Management of AIPs. Although current regulations do not require an ACO to spend its shared savings in any particular way, CMS proposes to specify how an ACO may use AIPs, citing three reasons:

- The purpose of AIPs,
- The fact that AIPs are made before any shared savings are actually earned by an ACO, and
- CMS' proposed limitations on the recovery of AIPs in the absence of earned shared savings.

Thus, an ACO must use AIPs to improve the quality and efficiency of items and services furnished to beneficiaries by investing in the following categories:

- Increased staffing,
- Health care infrastructure, and

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- The provision of accountable care for underserved beneficiaries, which may include addressing social determinants of health (SDOH).

CMS offers numerous examples of permitted uses within these three categories, while emphasizing that AIP amounts are advance shared savings and are not payment or reimbursement for items or services under the three specified categories. **CMS solicits comment on whether there are additional categories of expenses that should be permitted in light of the purposes of AIPs.**

In the preamble, CMS also provides examples of prohibited uses of AIPs, including management company or parent company profit, performance bonuses, other provider salary augmentation, provision of medical services covered by Medicare, or items or activities unrelated to ACO operations that improve the quality and efficiency of items and services furnished to beneficiaries. However, performance bonuses could be tied to successful implementation of SDOH screenings or care management guidelines, or ACOs could pay a higher salary as necessary to retain a clinician who treats underserved beneficiaries. The proposed regulation specifically prohibits AIPs from being used for any expense other than an allowable use or to repay shared losses of ACOs in Level E of the BASIC track. **CMS solicits comment on these examples of prohibited uses and whether there are additional categories of expenses that should be prohibited in light of the purposes of AIPs.**

To allow CMS to monitor whether the funds are used only for allowable uses and to ensure that AIPs do not pay for any prohibited uses, CMS proposes to require ACOs to segregate AIPs from all other revenues by establishing and maintaining a separate account into which the ACO must immediately deposit all AIPs and from which all disbursements of such funds are made only for allowable uses. Although CMS would deposit AIPs into the same account used for the deposit of shared savings payments, upon receipt of AIPs, the ACO must immediately deposit the funds into the separate AIP account.

AIP Methodology. During the first 2 performance years of the ACO's participation agreement, AIPs would include a one-time fixed payment of $250,000 and 8 quarterly payments based on the number of assigned beneficiaries (capped at 10,000 beneficiaries for AIP payment-calculation purposes). CMS believes that initial ACO start-up costs do not vary significantly by the size of an ACO or by the underlying level of risk of an assigned beneficiary population. However, **CMS seeks comment on the proposal to provide eligible ACOs with a one-time payment of $250,000, as well as alternatives such as allowing the one-time payment to vary based on the number of assigned beneficiaries, the risk factors of the ACO's assigned beneficiary population, or both.**

As with the one-time payment, the structure of the quarterly payments is informed by CMS' experience in AIM, where ACO participants had variable costs for clinical care management activities (such as clinical staff) supported by the per beneficiary per month payments. CMS considered monthly and additional annual payments. However, monthly payments would result in additional operation burden for CMS that is not feasible and offers little additional benefit to ACOs relative to quarterly payments, according to CMS. On the other hand, CMS believes the

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benefit to ACOs of consistent payments on a quarterly basis—compared to additional annual amounts—outweighs the administrative costs of calculating quarterly payments. **CMS seeks comment on the proposed schedule of the AIPs to ACOs.**

The ACO's upcoming quarterly payment amount would be determined prior to the start of each quarter based on the latest available assignment list for the performance year. (An alternative under consideration by CMS is based on the beneficiaries assigned to the ACO at the beginning of a performance year, which could remain fixed for the duration of that performance year. This would provide certainty regarding the amount of payments over the course of the year, but carries the risk that CMS would underpay or overpay relative to the quarterly determination. **CMS seeks comment on this alternative proposal for the quarterly payment determination.**)

The 8 quarterly AIPs would be based on the number of assigned beneficiaries (capped at 10,000), adjusted by a risk factors-based score for each beneficiary, taking into account dual-eligibility status and the ADI national percentile ranking of the census block group of the beneficiary's primary address. Specifically, CMS would complete the following steps to calculate the ACO's quarterly AIP amount:

- Step 1: Determine the ACO's assigned beneficiary population.
- Step 2: Assign each beneficiary a risk factors-based score, as follows:
    - 100 (producing maximum payment amount) if the beneficiary is dually eligible for Medicare and Medicaid—which corresponds to a quarterly payment of $45.
    - If the beneficiary is not dually eligible, assign a risk factors-based score equal to the ADI national percentile rank of the census block group corresponding with the beneficiary's primary mailing address.
    - 50 if the beneficiary is not dually eligible and cannot be matched with an ADI national percentile rank due to insufficient data—which corresponds to a quarterly payment of $28.
- Step 3: Determine the payment amount for each beneficiary, based on the risk factors-based score, shown below from Table 42 and proposed §425.630(f)(2)(iii).

Risk Factors-Based Score	**1-24**	**25-34**	**35-44**	**45-54**	**55-64**	**65-74**	**75-84**	**85-100**
Per beneficiary payment amount	$0	$20	$24	$28	$32	$36	$40	$45

- Step 4: Calculate the ACO's total quarterly payment amount. If the ACO has more than 10,000 assigned beneficiaries, CMS would calculate the quarterly payment amount based on the 10,000 assigned beneficiaries with the highest risk factors-based scores.

CMS offered various alternatives for the calculation of the quarterly AIPs, for which it seeks comments.

AIP Compliance and Monitoring. CMS proposes to monitor the spending of AIPs to provide CMS with a clear indication of how ACOs intend to spend AIPs, provide adequate protection to the Medicare Trust Funds, and to prevent funds from being misdirected or appropriated for

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activities that do not constitute a permitted use of the funds. CMS would compare the anticipated spending in the spend plan to the actual spending reported on the ACO's public reporting webpage, including any expenditures not identified in the spend plan. The reported annual spending must include any expenditures of AIPs on items not identified in the spend plan. ACOs would be required to annually report their actual expenditures via an updated spend plan on their public reporting webpage.

If CMS determines that an ACO had disbursed AIPs for a prohibited use, CMS could take compliance action in existing §§425.216 and 425.218 and could terminate the ACO's receipt of AIPs. Any AIPs that are unspent at the end of the ACO's agreement period must be repaid to CMS.

CMS is concerned about the possibility that an ACO may be eligible to receive AIPs and then quickly thereafter seek to add ACO participants experienced with performance-based risk, thereby avoiding the inexperience and low-revenue eligibility requirements. Therefore, CMS proposes to monitor ACOs that receive AIPs for changes in the risk experience of ACO participants that would cause an ACO to be considered experienced with performance-based risk or a high revenue ACO and therefore ineligible for AIPs. As proposed, the ACO would be obligated to repay spent and unspent AIPs if CMS takes pre-termination action under §425.216 and the ACO continues to be experienced with performance-based risk Medicare ACO initiatives or a high revenue ACO after a deadline specified by CMS pursuant to such compliance action (for example, the next deadline for updating the ACO participant list). To retain its AIP, an ACO that CMS determines to be experienced with performance-based risk or a high revenue ACO would be required to remedy the issue by the deadline specified by CMS. For example, if the ACO participants' total Medicare Parts A and B FFS revenue has increased in relation to total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, the ACO could remove an ACO participant from its ACO participant list so that the ACO could meet the definition of a low revenue ACO.

Although CMS' existing pre-termination actions for ACOs do not include the cessation of payments to an ACO, CMS proposes at §425.630(h) that it may immediately terminate an ACO's receipt of AIPs if the ACO does any of the following:

- Ceases to meet the eligibility requirements,
- Fails to comply with other AIP requirements, or
- Meets any of the grounds for termination set forth generally for ACOs at §425.218(b).

Recoupment. In AIM, CMS recouped prepaid shared savings from any shared savings earned by an ACO in its current agreement period, and if necessary, future agreement periods. If the ACO did not achieve shared savings, then the prepaid shared savings were not recouped. Additionally, the balance of funding was not recouped if the ACO completed the agreement period and decided not to reenroll in a second agreement period. However, if the ACO terminated prior to the end of its 3-year agreement period, the remaining balance was required to be repaid in full. During AIM, CMS observed that offering new small ACOs prepaid shared savings that they were not at risk of being forced to repay if they did not achieve savings was a critical incentive for small providers and suppliers to form ACOs to join AIM. This experience

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in AIM informs CMS' proposal at §425.630(g) for recoupment of the AIPs from an ACO in the Shared Savings Program, which now has 5-year agreement periods.

Regarding recoupment of AIPs, CMS proposes the following:

- AIPs are recouped from any shared savings earned by the ACO in any performance year until CMS has recouped all AIPs.
- If there are insufficient shared savings to recoup the AIPs in a performance year, that remaining balance would be carried over to the subsequent performance year(s) in which the ACO achieves shared savings, including any performance year(s) in a subsequent agreement period.
- CMS will not recover an amount of AIPs greater than the shared savings earned by an ACO in that performance year. Thus, if an ACO does not earn shared savings, none of the AIPs would be recouped from the ACO.
- If an ACO terminates its participation agreement during the agreement period in which it received an AIP, the ACO must repay all AIPs it received.
- The proposed regulation also contains details in the event of bankruptcy.

CMS seeks comment on all aspects of the proposals for recoupment of the AIPs made to ACOs.

b. Smoothing the Transition to Performance-Based Risk in ACOs

Background. CMS notes that the Shared Savings Program, since its inception in 2012, has included both one-sided financial models (also known as shared savings only, or upside only) and two-sided financial models (shared savings and shared losses, or upside and downside risk) for ACOs to select based on the arrangement that makes the most sense for their organization. Over the years, CMS has modified available financial models (participation options) providing "on-ramps" to attract both those that are new to value-based purchasing, as well as more experienced entities that are ready to accept two-sided risk. CMS has modified these participation options to adjust the maximum level of risk that must be assumed under two-sided models and to smooth the transition to two-sided models. In the preamble, CMS walks through the history of these modifications in the Shared Savings Program.

Most recently (December 2018 final rule at 83 FR 67822), CMS redesigned the participation options to transition more rapidly to two-sided models under two tracks—a BASIC track and an ENHANCED track. Both tracks are designed for 5-year agreement periods. The BASIC track includes a glide path with 5 Levels (A through E) that allows eligible ACOs to begin under a one-sided model for 2 years (each year of which is identified as a separate level (Levels A and B)) and advance to a two-sided model that includes incrementally higher levels of risk and reward (Levels C, D, and E) for the remaining 3 years of the agreement period. CMS allowed additional flexibility for new ACOs that qualify as low revenue ACOs inexperienced with performance-based risk Medicare ACO initiatives[5] to participate for up to 3 performance years under a one-sided model (4 performance years in the case of ACOs entering an agreement period

[5] Current regulations at §425.20 define "experienced with performance-based risk Medicare ACO initiatives" and "inexperienced with performance-based risk Medicare ACO initiatives."

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beginning on July 1, 2019) of the BASIC track's glide path before transitioning to the highest level of risk and potential reward under the BASIC track (Level E) for the final 2 years of the agreement period. Based on a combination of factors, CMS determines an ACO's eligibility for participation options in the BASIC track and ENHANCED track, along with the number of agreement periods that the ACO may participate in the BASIC track.

An ACO's ability to participate in the BASIC track is limited, and all ACOs eventually must transition to participation in the ENHANCED track to continue in the program. High revenue ACOs are limited to, at most, a single agreement period under the BASIC track prior to transitioning to participation under the ENHANCED track. Low revenue ACOs are generally limited to 2 agreement periods—for a total of 10 performance years—under the BASIC track. Current regulations require that should a low revenue ACO identified as experienced with performance-based risk Medicare ACO initiatives have changes in the revenue of its ACO participants that would cause the ACO to be considered a high revenue ACO (as these terms are defined in §425.20), the ACO must take corrective action or terminate its participation under the BASIC track by the end of the current performance year.

Many comments to the December 2018 final rule disagreed with the more aggressive transition of ACOs to performance-based risk. Some also noted that while this may increase ACO performance of those that continue to participate, it could reduce participation overall. CMS observed this with AIM participants, which meaningfully outperformed peer ACOs but then dropped out at an elevated frequency before even attempting to enter the one-sided model (upside-only) portion of the BASIC track glide path. CMS believes this suggests two things:

- While an upside-only participation option with a lower shared savings rate can be a highly effective incentive for smaller, low-revenue ACOs targeted by AIM, such ACOs also likely feel a correspondingly magnified disincentive to accept exposure to even the limited downside risk presented by the current BASIC track glide path.
- Not even superior performance under Track 1 appears to provide enough confidence for such ACOs to consistently move into participation options leading to assumption of two-sided risk.

In response to several commenters' concerns that requiring the rapid assumption of significant levels of risk by ACOs would discourage new participants and impede current ACOs' ability to make patient-centered infrastructure investments that are necessary for successful participation, CMS had stated its commitment to continue to monitor program participation and consider further refinements to the program's participation options. Most commenters on the participation options that were finalized in December 2018 recommended that CMS extend the time an ACO can participate in a one-sided model to 3 performance years, as opposed to the 2 performance years adopted generally under the BASIC track.

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Table 43, reproduced below, shows that 59 percent of the 483 ACOs are in a two-sided model.

TABLE 43: 2022 Shared Savings Program ACO Track Information

ACO Track	ACOs	Percent
One Sided (41% of ACOs)		
BASIC Track Levels A&B	199	41%
Two Sided (59% of ACOs)		
BASIC Track Levels C&D	40	8%
BASIC Track Level E*	98	21%
ENHANCED Track*	146	30%
TOTAL ACOs PY 2022	483	100%

*Qualifies as an Advanced Alternative Payment Model (APM).
Note: Tracks 1, 2, 3 and the Track 1+ ACO Model are no longer applicable as of PY 2022.

In 2020 and 2021, due to the PHE for COVID-19, CMS provided additional participation option flexibilities, allowing ACOs participating in the BASIC track's glide path the option to elect to forgo automatic advancement and "freeze" their participation for PY 2021 and PY 2022 at their PY 2020 and 2021 levels, respectively. CMS reports that 140 out of 157 (89 percent) currently participating ACOs chose to maintain their participation in a one-sided model rather than move to risk for PY 2021, and 103 out of 140 (74 percent) for PY 2022.

CMS believes it would be prudent to provide greater flexibility for ACOs to join the program under one-sided risk and to remain in the program under lower levels of performance-based risk in order to balance CMS' desire to see more ACOs participate under performance-based risk while also working toward the goal of increasing overall Shared Savings Program participation and improving outcomes for beneficiaries. CMS believes it would be appropriate to allow certain ACOs in their first agreement period in the program to maintain participation in a one-sided model (with a lower sharing rate) for a longer period of time, rather than risk having those ACOs leave the program altogether to avoid transitioning to two-sided risk. Even if an ACO does not earn shared savings, ACOs have demonstrated that they are likely saving Trust Fund dollars by modifying their ACO participants' behavior to coordinate care and carry out other interventions to improve quality and financial performance.

CMS is also concerned that the current policy of considering an ACO's status as a high- or low-revenue ACO in determining the participation options available to the ACO may disincentivize certain providers from forming ACOs or joining existing ACOs. CMS also believes ACOs inexperienced with performance-based risk Medicare ACO initiatives, regardless of their status as a high- or low-revenue ACO, may be more likely to participate in the program if they are allowed more time under a one-sided model than is currently allowed.

Proposal for a 5-Year Agreement Period under a One-Sided Model for Eligible ACOs. In light of the foregoing considerations and others described in the preamble, CMS is proposing to allow certain ACOs more time under a one-sided model and more flexibility in transitioning to higher levels of risk and potential reward by modifying the participation options available under the Shared Savings Program. Currently participating ACOs, or ACOs that begin an agreement period in Level A or Level B on January 1, 2023, may elect to maintain their participation at Level A or Level B for the remainder of their current agreement period. Because the annual

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application and change request cycle will begin before the 2023 PFS final rule is issued, CMS will give ACOs currently participating in Level A or B of the BASIC track glide path the opportunity during the change request cycle to indicate whether they are interested in maintaining their participation at Level A or Level B under this proposed policy, should it be finalized.

All other policies proposed in this section would be effective for agreement periods starting on or after January 1, 2024, unless otherwise noted.

CMS proposes to allow an ACO entering the BASIC track's glide path at Level A that is currently at Level A to elect to remain in Level A for all subsequent performance years of the agreement period—if the following requirements are met:

- The ACO is participating in its first agreement period under the BASIC track,
- The ACO is not participating in an agreement period under the BASIC track as a renewing ACO or a re-entering ACO that previously participated in the BASIC track's glide path under §425.600(a)(4), and
- The ACO is inexperienced with performance-based risk Medicare ACO initiatives.[6]

This voluntary election could occur prior to the automatic advancement of the ACO to Level B and would be made in the form and manner and by a deadline established by CMS.

In the case of an ACO that elects to remain in Level A for the entirety of its first agreement period, the ACO generally would be eligible to enter into a subsequent agreement period under the BASIC track's glide path, giving the ACO 2 additional years of one-sided risk. Thus, if an eligible ACO made this election and did not elect faster advancement to a higher level of risk and potential reward, the ACO would have 7 years under one-sided risk. Currently, ACOs inexperienced with performance-based risk Medicare ACO initiatives generally are limited to 2 years under a one-sided model, which ACOs have informed CMS is not enough time before transitioning to risk.

CMS also proposes permitting an ACO that is inexperienced with performance-based risk Medicare ACO initiatives to participate in the BASIC track glide path for a maximum of 2 agreement periods (once at Level A for all 5 performance years and a second time in progression on the glide path). This option is limited in that an ACO that enters an agreement at either Level A or Level B is deemed to have completed one agreement under the BASIC track's glide path and is only eligible to enter a second agreement under the BASIC Track's glide path if the ACO continues to meet the definition of inexperienced with performance-based risk Medicare ACO initiatives and satisfies either of the following:

- The ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track's glide path only one time; or
- For a new ACO identified as a re-entering ACO, the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track's glide path only one time.

[6] CMS notes this would not exclude re-entering former Track 1 ACOs.

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CMS proposes that an ACO determined to be inexperienced with performance-based risk Medicare ACO initiatives but not eligible to enter the BASIC track's glide path may enter either the BASIC track Level E for all performance years of the agreement period, or the ENHANCED track.

CMS proposes to amend the definition of performance-based risk Medicare ACO initiative at §425.20 to include only Levels C through E of the BASIC track, removing the one-sided Levels A and B from the definition. CMS further proposes updating the definitions of inexperienced with performance-based risk Medicare ACO initiatives and experienced with performance-based risk Medicare ACO initiatives to allow for a rolling lookback period of the 5 most recent performance years.

In determining an ACO's eligibility to participate under the proposed new participation options, CMS proposes considering only an ACO's experience with performance-based Medicare ACO initiatives, not the ACO's status as a high- or low-revenue ACO. CMS also proposes to make the ENHANCED track optional for all ACOs, regardless of experience with performance-based risk Medicare ACO initiatives, including high-revenue ACOs.

If an ACO meets the definition of experienced with performance-based risk Medicare ACO initiatives, CMS proposes that the ACO would be permitted to complete the remainder of its current performance year in a one-sided model of the BASIC track, but would be ineligible to continue participation in the one-sided model after the end of that performance year if it continues to meet the definition of experienced with performance-based risk Medicare ACO initiatives and would be automatically advanced to Level E of the BASIC track at the start of the next performance year.

CMS seeks comment on the foregoing proposals for ACO participation options in the Shared Savings Program, as well as potential alternatives detailed in the preamble.

Proposal to Remove the Limitation on the Number of Agreement Periods an ACO can Participate in Level E of the BASIC Track. Currently, there are limitations on how long ACOs may participate (if at all) in the BASIC track, including at Level E, the BASIC track's highest level of risk and potential reward. Some ACOs have reported that they would rather leave the program than be required to move to the ENHANCED track and have requested that CMS make the ENHANCED track optional for ACOs. CMS now believes it would be in the best interest of the program and Medicare FFS beneficiaries to permit eligible ACOs to continue participating under the BASIC track Level E, rather than risk significant numbers of experienced, successful ACOs terminating their participation in the program instead of progressing to the ENHANCED track. CMS proposes that if an ACO is determined to be experienced with performance-based risk Medicare ACO initiatives, the ACO may enter BASIC track Level E for all performance years of the agreement period, or the ENHANCED track. These options would be available without regard to the ACO's status as a high- or low-revenue ACO. CMS also proposes that all ACOs would be permitted to participate indefinitely under the BASIC track Level E, or the ENHANCED track.[7]

[7] This would include ACOs currently in the ENHANCED track or that participate under the ENHANCED track in

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CMS anticipates providing education and offering outreach to ACOs on the available participation options through various methods—including ACO Coordinators, guidance documents, tip sheets, FAQs, and a bi-weekly newsletter.

3. Determining Beneficiary Assignment Under the Shared Savings Program

CMS reviews the evolution of beneficiary assignment to Shared Savings Program ACOs, beginning with the November 2011 rule in which assignment based upon primary care services delivered was established and the initial list of primary care services adopted for that purpose (76 FR 67853). Periodic updates of the list have been made to reflect changing service codes (e.g., addition of chronic care management services) and approaches to beneficiary assignment (e.g., addition of voluntary assignment).

a. Revised Definition of Primary Care Services (§425.400(c))

CMS proposes to add for PY 2023 and subsequent years the following 4 services and provides rationales for adding them to the beneficiary assignment code list. These HCPCS G-codes are proposed for payment under the PFS in sections II.E. and II.F. of the rule where they are discussed in detail. The complete list of codes to be used for Shared Savings Program assignment purposes beginning with PY 2023 is provided at the end of this section.

(1) Prolonged Services

- GXXX2 Prolonged nursing facility evaluation and management service(s) beyond the total time for the primary service, each additional 15 minutes

This code would be added to an initial or subsequent nursing facility visit (CPT codes 99306 and 99310, respectively) for each 15-minute increment once the time spent by the physician or non-physician practitioner (NPP) exceeds 95 minutes for an initial visit or 85 minutes for a subsequent visit. CMS believes it appropriate to add this code to the assignment list because its base codes are already included on the list.

- GXXX3 Prolonged home or residence evaluation and management service(s) beyond the total time for the primary service, each additional 15 minutes

This code would be added to an initial or subsequent home or residence visit (CPT codes 99345 and 99350, respectively) for each 15-minute increment once the time spent by the physician or NPP exceeds the times for these visits plus an additional 15 minutes. The base times for these visits have not yet been finalized. CMS believes it appropriate to add this code to the assignment list because its base codes are already included on the list.

the future. These ACOs would be permitted to enter a new participation agreement under Level E of the BASIC track.

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(2) Chronic Pain Management Services

- GYYY1 Chronic pain management and treatment, monthly bundle

CMS proposes to add this code to the beneficiary service assignment list, believing it to be similar to existing chronic care management and principal care management services (CPT codes 99430 and 99425, respectively) that are already included on the list. CMS also notes that the monthly bundle includes elements very similar to the elements required for these reference codes (e.g., care plan, medication management, care coordination).

(3) Primary Care Service Codes for Shared Savings Program Beneficiary Assignment as Proposed for PY 2023 and Subsequent Years

CPT Codes

- 96160 and 96161 (administration of health risk assessment).
- 99201 through 99215 (office or other outpatient visit for the evaluation and management of a patient).
- 99304 through 99318 (professional services furnished in a nursing facility; services identified by these codes when furnished in a skilled nursing facility are excluded when reported on claims from Federally Qualified Health Centers or Rural Health Clinics).
- 99319 through 99340 (patient domiciliary, rest home, or custodial care visit).
- 99341 through 99350 (evaluation and management services furnished in a patient's home).
- 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code).
- 99421 through 99423 (online digital evaluation and management)
- 99424 through 99427 (principal care management services)
- 99437, 99487, 99489, 99490, and 99491 (chronic care management services)
- 99439 (non-complex chronic care management).
- 99483 (assessment and care planning for patients with cognitive impairment).
- 99484, 99492, 99493 and 99494 (behavioral health integration services).
- 99495 and 99496 (transitional care management services).
- 99497 and 99498 (advance care planning; excluded when provided in inpatient settings).

HCPCS codes:

- G0402 (Welcome to Medicare visit).
- G0438 and G0439 (annual wellness visits).
- G0442 (alcohol misuse screening service).
- G0443 (alcohol misuse counseling service).
- G0444 (annual depression screening service).
- G0463 (services furnished in Electing Teaching Amendment hospitals).
- G0506 (chronic care management).

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- G2010 (remote evaluation of patient video/images).
- G2012 (virtual check-in, 5-10 minutes).
- G2058 (non-complex chronic care management).
- G2064 and G2065 (principal care management services).
- G2212, GXXX2 and GXXX3 (prolonged office or other outpatient evaluation and management services)
- G2214 (Psychiatric collaborative care model).
- GYYY1 and GYYY2 (chronic pain management services)

b. Technical Update to Home and Residence Services (CPT Codes 99341 through 99350)

CMS proposes to incorporate updated CPT guidelines for Home and Residence Services into policies for the Shared Savings Program's primary care service list. The updated guidelines will take effect starting with the CPT 2023 edition to services furnished in assisted living facilities, group homes, custodial care facilities, and residential substance abuse facilities as well as to beneficiary homes. CMS discusses this change more fully in section II.C. of the rule and proposes there to adopt the updated guidelines under Medicare Fee for Service policies for 2023 and subsequent years.

To implement the update, CMS proposes to add a revised list of primary care services at §425.400(c)(1)(vii)(A)(7) for PY 2023 and subsequent years. The revised list will omit prior references to place of service modifier 12 associated with CPT codes 99341-99350, as place of service 12 would no longer describe the beneficiary group receiving these services.[8]

c. Rural Emergency Hospitals (REHs)

CMS states that it is not proposing to adopt special policies for treatment of services furnished in REHs for purposes of beneficiary assignment under the Shared Savings Program. For assignment purposes, CMS plans to treat services provided in REHs in the same manner as hospital outpatient department services are treated currently by the agency.

d. Using CMS Certification Numbers (CCNs) During Beneficiary Assignment

CMS proposes revisions to the process whereby certain facilities are identified for use in beneficiary assignment, including when a facility's CCN enrollment changes during a Shared Savings Program performance year. The revised process would be applicable starting with PY 2023 and subsequent years for Federally Qualified Health Centers (FQHCs), Rural Health Clinics (RHCs), Electing Teaching Amendment (ETA) hospitals, and Method II Critical Access Hospitals (CAHs). The revised process is described below and would be codified in a new section at §425.402(f).

- Before a performance year starts and periodically during the year, CMS will determine the CCNs for all FQHCs, RHCs, Method II CAHs, and ETA hospitals enrolled under the TIN of an ACO participant. This will include all CCNs with an active Medicare

[8] Place of service 12 is defined by CMS as "location, other than a hospital or other facility, where the patient receives care in a private residence."

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enrollment and all CCNs having a deactivated enrollment status. These CCNs will be used in determining assignment for the performance year.

- CMS will account for CCN enrollment status changes during the performance year as follows:
  - If a CCN with no prior Medicare claims experience enrolls under the TIN of an ACO participant after the ACO certifies its required annual ACO participant list, CMS will consider services furnished by that CCN when determining beneficiary assignment to the ACO if the ACO has elected preliminary prospective assignment with retrospective reconciliation for that year.
  - Services furnished by a deactivated CCN that is listed as an ACO participant when a performance year starts will be considered in determining beneficiary assignment to the ACO for the applicable performance year or benchmark year.
  - For a CCN enrolled under the TIN of an ACO participant when a performance year starts then enrolls under a different TIN during the year, CMS will continue to treat services billed by the CCN as services furnished by the ACO participant it was enrolled under at the start of the performance year for purposes of determining beneficiary assignment to the ACO for the applicable performance year.

CMS believes the proposed process will more accurately capture changes to providers and suppliers that participate in an ACO for a given performance year. CMS emphasizes the importance both to CMS and ACOs of accurate participant, provider/supplier, and attestation lists for use in beneficiary assignment, quality measurement, and compliance activities.

4. Quality Performance Standard and Reporting Requirements (§425.512)

The Shared Savings Program'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. As a result of prior rulemaking, the standard's performance parameters and its associated reporting requirements are set to gradually increase during PY 2023 and PY 2024 before stabilizing for PY 2025 and subsequent years (86 FR 65263). During the transition, ACOs may report either through the CMS Web Interface or using the electronic clinical quality measures (eCQMs) or clinical quality measures (CQMs) of the APM Performance Pathway (APP) of the Merit-based Incentive Payment System (MIPS).[9] Beginning with PY 2025, only the APP reporting mechanism will be available.

In this rule, CMS proposes to add an alternative quality performance standard, base shared savings and loss amounts on sliding scales, and extend the transition period's existing incentive for reporting the APP measures. CMS also proposes to implement a health equity adjustment to ACO quality scores based on beneficiary dual eligibility and residence in a disadvantaged neighborhood. Minor changes are proposed for Web Interface and APP measures. Proposals are made to address interactions between the alternative quality standard and Advanced APM status. CMS invites comment on all proposals, particularly those related to sliding scales for shared

[9] During the transition, if an ACO successfully reports both through the Web Interface and the APP, the higher of its overall quality scores will be used to determine shared savings eligibility and shared savings/loss amounts.

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savings and losses. No changes are proposed to the pay-for-reporting performance standard that applies only to ACOs in the first year of their first Shared Savings Program agreement period (§425.512(a)(2)). CMS discusses a process under consideration for reopening ACO financial performance determinations when quality score errors are subsequently discovered through MIPS targeted reviews. Finally, CMS issues Requests for Information (RFIs) related to beneficiary screening for health-related social needs and about adding questions to the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey.

a. Alternative Quality Performance Standard

CMS proposes to revise the Shared Savings Program's quality performance standard by adding a new, less stringent "alternative" quality performance standard beginning with PY 2023. Under the proposed standard, an ACO achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least 1 of 4 outcome measures in the APP measure set would be eligible for shared savings. The existing standard would be retained (30th percentile for PY 2023), modified to include the proposed health equity adjustment if finalized (described later in the rule and this summary). Proposed performance parameters of the two standards and their associated reporting requirements are shown in Table 51 of the rule and below. The requirement to field the CAHPS for MIPS survey applies to both the existing and proposed alternative quality performance standards.

Each ACO's performance would be assessed using both standards. An ACO meeting the existing standard would continue to be eligible for the maximum shared savings associated with its track and level (e.g., 50% for BASIC Level E). An ACO that meets only the alternative standard would be eligible to receive shared savings but in a lesser, scaled amount than under the existing standard. An ACO that meets neither the existing or alternative standard would be ineligible for shared savings.

CMS makes this proposal to mitigate the "all-or-none" scoring structure of the existing standard (i.e., maximum shared savings or none), allowing more ACOs to realize at least some shared savings. CMS believes that increasing access to shared savings is particularly important during the ongoing transition to higher performance parameters and will facilitate retention and recruitment of ACOs into the Shared Savings Program.

CMS states similar reasons for making a parallel proposal regarding shared losses accrued by ACOs bearing two-sided risk, discussed further below. If those ACOs meet only the alternative quality performance standard, they would be eligible for reduced repayments of their losses. The reduction would be smaller than had the ACO met the existing standard.

Table 51. Proposed Reporting Requirements and Quality Reporting Standard for PY 2023 and Subsequent PYs
(From Table 51 in the rule with formatting modifications)

	PY 2023	**PY 2024**	**PY 2025 and Subsequent Years**
Quality Reporting Requirements	Report 10 Web Interface measures **or** the 3 APP eCQMs/MIPS CQMs; **and** administer CAHPS for MIPS	Same as PY 2023	Report the 3 APP eCQMs/MIPS CQMs; **and** administer CAHPS for MIPS

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Table 51. Proposed Reporting Requirements and Quality Reporting Standard for PY 2023 and Subsequent PYs (From Table 51 in the rule with formatting modifications)			
	PY 2023	**PY 2024**	**PY 2025 and Subsequent Years**
	survey. CMS calculates 2 claims-based measures.		survey. CMS calculates 2 claims-based measures.
Existing Quality Performance Standard Revised to Include the Proposed Health Equity Adjustment	A health-equity adjusted score that is equivalent to or ≥ the **30th percentile** across all MIPS Quality performance category scores (excludes those eligible for facility-based scoring*) **OR** Report 3 APP eCQMs/MIPS CQMs (for each, meet completeness and case minimum requirements); achieve quality performance score equivalent to or >**10th percentile** of performance benchmark on ≥ 1 (of 4) **APP outcome** measures and a score equivalent to or > than the **30th percentile** of performance benchmark on ≥ 1 of 5 remaining APP measures	A health-equity adjusted score that is equivalent to or ≥ the **40th percentile** across all MIPS Quality performance category scores (excludes those eligible for facility-based scoring*) **OR** Report 3 APP eCQMs/MIPS CQMs (for each, meet completeness and case minimum requirements); achieve quality performance score equivalent to or >**10th percentile** of performance benchmark on ≥ 1 (of 4) **APP outcome** measures and a score equivalent to or > than the **40th percentile** of performance benchmark on ≥ 1 of 5 remaining APP measures	A health-equity adjusted score that is equivalent to or ≥ the **40th percentile** across all MIPS Quality performance category scores (excludes those eligible for facility-based scoring*)
Alternative Quality Performance Standard	Fails to meet **2023** criteria above but ACO Quality performance score equivalent to or > than **10th percentile** of performance benchmark on ≥ 1 (of 4) APP outcome measures would allow shared savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality performance score	Fails to meet **2024** criteria above but ACO Quality performance score equivalent to or > than **10th percentile** of performance benchmark on ≥ 1 (of 4) APP outcome measures would allow shared savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality performance score	Fails to meet **2025** criteria above but Quality performance score equivalent to > than **10th percentile** of performance benchmark on ≥ 1 (of 4) APP outcome measures would allow shared savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality performance score
Quality Performance Standard - Standard is NOT Met	If an ACO (1) does not report any of the 10 CMS Web Interface measures or any of the 3 APP eCQMs/MIPS CQMs **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.	Same as PY 2023	If an ACO (1) does not report any of the 3 APP eCQMs/MIPS CQMs **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.
*Facility-based scoring allows certain clinicians (e.g., pathologists) to be scored using their facilities' Hospital Value Based Purchasing Program results.			

b. Scaled Shared Savings (§§425.605 and 425.610)

Beginning with PY 2023, CMS proposes to adopt a sliding scale approach to calculate shared savings for BASIC and ENHANCED track ACOs that meet the proposed alternative quality

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performance standard but not the existing standard. The sliding scale approach would be agnostic to the ACO's quality data reporting mechanism (Web Interface or APP). The ACO's quality performance score would be multiplied by the maximum sharing rate allowed by the ACO's track and level, as shown below. CMS plans to use the proposed health-equity adjusted quality performance score, described later in the rule and this summary, for the scaled shared savings calculation. An example calculation is described in section III.G.4.b.(2) of the rule.

Proposed scaled shared savings rate = health-equity adjusted quality score x maximum shared savings rate for ACO track and level

CMS notes that a sliding scale approach to shared savings has been used previously in the Shared Savings Program. To maximize the amount received by each ACO eligible for shared savings, however, CMS replaced the sliding scale with the all-or-none approach during CY 2021 PFS rulemaking. The agency states that its proposal to return to a sliding scale is responsive to stakeholder concerns about declining scores caused by the transition to the APP measure set. Under the APP reporting mechanism (1) ACO performance will be compared to all MIPS eligible clinicians rather than only to other Shared Savings Program ACOs, (2) measures include patient data regardless of payer rather than only Medicare beneficiaries, and (3) small differences in MIPS quality score distributions could markedly change the number of ACOs that qualify for shared savings.

In addition to meeting quality standard and reporting requirements, to be eligible for shared savings, an ACO must first meet the minimum savings rate (MSR) requirement for its track and level. CMS later in the rule proposes to enable certain low-revenue ACOs in the BASIC track to share in savings even if the ACO does not meet its MSR. Criteria for such ACOs are proposed in a new provision at §425.605(h) and would apply to ACOs entering a BASIC track agreement period beginning January 1, 2024 or in subsequent years. An ACO that satisfies the specified criteria and meets the quality reporting standard would be eligible to receive shared savings at one-half of the maximum sharing rate for their track and level. The applicable quality standard used would be the existing standard but modified to utilize the proposed health equity-adjusted performance score. The reader is referred to section III.G.5.f(2) of the rule and to the Financial Methodology section of this summary below for further discussion.

c. Scaled Shared Losses (§425.610)

CMS proposes two revisions to the current sliding scale approach to calculating shared losses for Shared Savings Program ENHANCED track ACOs beginning with PY 2023. First, eligibility for the scaled loss approach would be expanded beyond ACOs meeting the existing quality performance standard to include those meeting the proposed alternative quality standard. Second, the shared loss rate calculation would be modified by replacing the current multiplier (MIPS quality performance category points earned ÷ total available points) with the proposed health-equity adjusted quality performance score, as shown below. The track's 75 percent maximum loss rate and 40 percent minimum loss rate would remain unchanged. An example calculation is described in section III.G.4.b.(3) of the rule.

Proposed scaled shared loss rate = 1 – (health-equity adjusted quality score x 75%)

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CMS believes that the proposed changes would make scaled (i.e., smaller) shared losses available to some ACOs that would otherwise face the maximum shared loss rate of 75 percent and would make the formula easier to understand without materially changing the methodology.

d. Interactions Between the Alternative Quality Standard and Advanced APM Status of ACOs

CMS discusses a potential conflict between the proposed alternative standard and the existing criteria for determining Advanced APM status. ACOs in the ENHANCED track and in Level E of the BASIC track that satisfy the existing Shared Savings Program's quality standard also meet the Advanced APM criterion that calls for payment to be contingent upon performance on at least 2 MIPS quality measures, one or more of which must be an outcome measure(s).[10] The APM criterion would not be satisfied by an ACO meeting only the proposed alternative quality performance standard since it requires just one measure. An ACO meeting only the alternative standard could earn scaled shared savings but would no longer qualify as an Advanced APM, and its clinicians would not receive credit towards APM Qualifying Participant status and its associated positive payment adjustments.

CMS notes that the conflict would be eliminated if a change to modify the Advanced APM quality criterion to require only one measure that is also an outcome measure is finalized as proposed in section IV.A.4.a. of the rule. If that proposal is not finalized, CMS plans to consider finalizing an alternative policy that would allow scaled shared savings beginning with PY 2023 and for subsequent years when an ACO (1) scores at or above the 10th percentile on one measure, (2) scores at or above the 30th percentile on a second measure, and (3) one of its two scored measures is an outcome measure. The alternative policy also would satisfy the existing Advanced APM quality criterion and allow the ACO to maintain its Advanced APM status. Concomitantly, if the revised Advanced APM quality criterion is not finalized as proposed, CMS would consider a parallel alternative policy applicable to scaled shared losses incorporating the same 3 elements described for the scaled shared savings policy.

e. Extension of eCQM/MIPS CQM Transition Incentive

CMS proposes to extend the incentive for ACOs to transition from reporting quality data through the CMS Web Interface to using the APP's eCQMs/CQMs measure set. The incentive, currently applicable through PY 2023, allows an ACO to meet the existing quality performance standard by (1) reporting 3 APP eCQMs/MIPS CQMs, meeting completeness and case minimum requirements for each, (2) scoring at or above the 10th percentile on one or more APP outcome measures, and (3) scoring at or above the 30th percentile on one or more of the remaining APP measures. The extension would apply through PY 2024 and for that year would specify scoring at or above the 40th percentile, rather than at the 30th percentile as currently specified.

CMS also requests comment on a related issue. If the MIPS Advanced APM quality criterion is revised as proposed in section IV.A.4.a of the rule (i.e., to require only one measure that is also

[10] Measures not included in the MIPS inventory may satisfy the requirement under certain specified circumstances. See §414.1415(b)(2) and (b)(3).

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an outcome measure), CMS is considering incorporating that change into the ACO quality reporting transition incentive by dropping the incentive's 30th or 40th percentile scoring requirement (for PY 2023 and PY 2024 respectively). The net result would be that an ACO could qualify for the incentive – and thereby meet the quality performance standard – for PY 2023 and PY 2024 solely by (1) reporting 3 APP eCQMs/MIPS CQMs, meeting completeness and case minimum requirements for each and (2) scoring at or above the 10th percentile on one or more APP outcome measures.

The quality standard requirements for PY 2025 and subsequent years as proposed do not interact with the proposed MIPS quality criterion revision. To meet the PY 2025 standard an ACO would be required to (1) report 3 APP eCQMs/MIPS CQMs, meeting completeness and case minimum requirements for each and (2) achieve a health-equity adjusted score that is equivalent to or above the 40th percentile across all MIPS Quality performance category scores (excluding those eligible for facility-based scoring).

f. Health Equity Adjustment

CMS proposes to adopt a health equity adjustment into the Shared Savings Program beginning with PY 2023. The adjustment would be incorporated into calculation of quality performance scores and shared savings and losses and into the extreme and uncontrollable circumstances policy. CMS further proposes that ACO eligibility for the adjustment would be determined by the proportion of assigned beneficiaries that are dually eligible or reside in disadvantaged neighborhoods and would be restricted to ACOs with relatively higher quality performance scores. The adjustment would be implemented through two proposed quality performance score adjusters and be capped at 10 points.

CMS believes that the proposed approach would appropriately award delivery of high-quality care to all patients served by an ACO, incent ACOs to include vulnerable patient groups and providers who treat them, reduce healthcare disparities, and extend accountable care relationships to more Medicare beneficiaries. CMS further believes that this approach avoids potential pitfalls of using risk adjustment methods to advance equity such as masking disparities and setting lower quality of care standards for underserved populations.

(1) Identifying Eligible ACOs

CMS proposes that the health equity adjustment would be available only to ACOs that report using the 3 eCQMs/MIPS CQMs of the APP measure set and meet data completeness requirements for each of these all-payer measures. In addition, the ACO would be required to field the CAHPS for MIPS survey. CMS would continue to calculate scores on two claims-based measures. ACOs reporting quality data only through the CMS Web Interface would not be eligible for the adjustment.

(2) Performance Grouping and Measure Performance Scaler

CMS proposes to link ACO eligibility for the health equity adjustment to performance on all 6 APP measures (eCQMs/MIPS CQM, CAHPS, and claims). ACOs would be divided into thirds, creating top, middle, and bottom "performance groups". Groups would be created independently for each of the 6 measures to capture performance variations within ACOs across measures.

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Performance grouping also would take reporting mechanism into account. ACOs reporting eCQMs would be compared only to other eCQM reporters and ACOs reporting MIPS CQMs would be compared only to other MIPS CQM reporters. Comparisons for the CAHPS and claims-based measures would take into account all ACOs submitting data for those measures.

CMS proposes to assign a value from zero to 4 for each measure for each ACO: a value of 4 for top performers, 2 for middle performers, and zero for bottom performers. The values would be summed into a "measure performance scaler", ranging from 0 to 24 points. CMS also would assign a value of zero for a measure for which the case minimums or sample size is not met by an ACO. However, CMS would still calculate a measure performance scaler using all measures for which complete data are available as long as data for at least the 3 eCQM/MIPS CQM measures are complete. Example calculations for the measure performance scaler are described in section III.G.4.b(7)(f) and Table 47 of the rule.

CMS indicates having considered other performance value assignment distributions and use of a 0/1/2 value set is discussed in detail. CMS states that the chosen 0/2/4 value set maximizes the health equity adjustment points awarded to high-performing ACOs with larger proportions of beneficiaries from underserved populations.

(3) Underserved Multiplier

CMS proposes to award higher positive health equity adjustments to ACOs with larger proportions of assigned beneficiaries from underserved populations. For this purpose, CMS is proposing to use the proportions of dually eligible beneficiaries and those residing in socioeconomically disadvantaged neighborhoods as reflected through the Area Deprivation Index (ADI).[11] The "underserved multiplier" could range between zero and 1 and would be set as the higher of an ACO's assigned beneficiary population that (1) are dually eligible or (2) reside in a census block group with an ADI national percentile rank of 85 or greater. Both the underserved multiplier and the previously described measure performance scaler would be used in calculating an ACO's health equity adjustment.

CMS believes that dual eligibility more closely reflects characteristics of underserved beneficiaries at the individual level (e.g., income) while the ADI more broadly reflects neighborhood level characteristics (e.g., employment, housing) that may influence the healthcare delivered to the neighborhood's residents.[12] As such, CMS sees the two proportions as complementary adjusters indicating potentially underserved status but with some degree of overlap. By proposing to use the higher adjuster's value, CMS seeks to more fully capture important determinants of healthcare outcomes while minimizing beneficiary double-counting due to overlap.

CMS also considered two alternatives: (1) the underserved multiplier is the sum of the dual and high ADI proportions or (2) the proportion of assigned beneficiaries eligible for the Part D low-

[11] The census block-level ADI is based on a measure created by the Health Resources and Services Administration (HRSA) and refined by researchers at the University of Wisconsin.

[12] CMS states that an ADI percentile rank of 85 or greater has been correlated with worse health outcomes such as increased rates of hospitalizations for conditions including heart failure and pneumonia.

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income subsidy (LIS) is added as a third adjuster for consideration – either to replace the dual proportion or used in a three-way comparison of adjuster values to determine the highest value, which would be used. A more detailed discussion is provided in section III.G.4.(7)(a) of the rule. **CMS specifically seeks comment on potential inclusion of the LIS proportion as part of the underserved multiplier.** CMS notes that LIS subsidy eligibility is standardized nationally whereas Medicaid eligibility varies across states. Additionally, CMS notes the ADI represents an all-payer population whereas dual eligibility and the LIS are linked specifically to Medicare as a payor.

(4) Determining Health Equity Adjustment Bonus Points and Health Equity-Adjusted Quality Performance Scores

CMS proposes to apply the health equity adjustment to payment in the form of bonus points added to an ACO's MIPS Quality performance category score (i.e., score for the APP measure set). The bonus points would equal the product of the performance scaler, the underserved multiplier and the performance score, and the sum of the bonus points and the MIPS quality score would be termed the health equity-adjusted quality performance score, as shown below.

Proposed health-equity adjustment bonus points = MIPS Quality performance category score x measure performance scaler x underserved multiplier

Proposed health-equity adjusted quality performance score = MIPS Quality performance category score + health-equity adjustment bonus points

CMS further proposes:

- to cap the health-equity adjustment bonus points at 10,
- to cap the health-equity adjusted quality performance score at 100 percent, and
- to set a floor, such that an ACO with an underserved multiplier of less than 20 percent would be ineligible to receive any bonus points.

CMS estimates that 30 percent of ACOs would have an underserved multiplier above 20 percent and expects that setting a floor of 20 percent would help to direct bonus points towards ACOs caring for significant numbers of underserved beneficiaries, increasing their quality performance scores. CMS anticipates that higher health equity-adjusted scores could enable those ACOs to meet the quality performance standard (or the alternative standard if finalized) and earn shared savings or have their shared losses reduced. Enhanced financial stability could incent these ACOs to remain in the Shared Savings Program and attract to the program new provider groups that care for large numbers of underserved beneficiaries.

(5) Calculation Steps and Examples

In section III.G.4.b(7)(f) of the rule CMS reviews the series of calculations to determine health equity adjustment bonus points and health equity-adjusted quality performance scores and shows examples for each step across a range of ACO characteristics and performances (Tables 47 through 50). The steps followed and the results for example ACO #3 are provided below.

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Step 1: Calculate the measure performance scaler. ACO #3 measure scores fall into the top performing group for 3 measures and the middle group for 3 measures. The ACO is assigned a value of 4 for 3 measures and a value of 2 for 3 measures; when summed, the assigned values total to a measure performance scaler of 18.

Step 2: Calculate the underserved multiplier. ACO #3 has a dual eligible beneficiary proportion of 0.3 and a proportion of beneficiaries residing in census blocks with ADIs of 85 or greater of 0.3. The "higher value" is 0.3. which becomes the underserved multiplier.

Step 3: Calculate the health equity bonus points. Multiply the results of steps 1 and 2. ACO #3 is awarded 5.4 bonus points (18 x 0.3).

Step 4: Calculate the equity-adjusted performance score. Add the bonus points to the MIPS Quality category performance score. For ACO #3, 5.4 bonus points are added to its MIPS quality score of 85.0 to give a health equity-adjusted quality performance score of 90.4 for ACO #3.

CMS describes a plan to include the health equity adjustment calculations and their results for an ACO as part of its financial reconciliation reports package if the ACO has reported data for the APP's eCQM/MIPS CQMs, even if the ACO also reported data through the CMS Web Interface.

CMS notes that an ACO submitting both APP and Web Interface measure data will be assigned the higher of its 2 resulting MIPS quality category performance scores. However, if adding the ACO's bonus points to its APP-based performance score results in an equity-adjusted performance score higher than the Web Interface-based quality score, the higher equity-adjusted score will be used as the ACO's quality performance score for determining shared savings eligibility and calculating shared savings and losses. CMS emphasizes that MIPS quality category scoring for the ACO's clinicians uses the higher of the ACO's APP-based or Web Interface-based scores prior to any bonus point addition (i.e., the equity-adjusted quality score is not used when scoring the MIPS Quality performance category at the individual MIPS clinician level).

(6) Extreme and Uncontrollable Circumstances Policy (§425.512(b))

CMS proposes to specify that the health equity-adjusted quality performance score would be taken into consideration when determining the quality performance score and calculating shared savings/shared loss reductions for an ACO that has been affected by extreme and uncontrollable circumstances. CMS notes, however, that substituting the equity-adjusted score for the unadjusted score would have limited impact because the current extreme and uncontrollable circumstances policy already assigns to an affected ACO a MIPS quality performance category score that is sufficient to qualify for shared savings/shared loss reductions (e.g., 30th percentile across MIPS quality measures for PY 2023).

More specifically, CMS also notes that:

- Per existing policy, an affected ACO would qualify for the maximum shared savings rate for its track and level and that is not changed by proposals in this rule.

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- Per existing policy, an affected ACO on the ENHANCED track and liable for shared losses already receives a shared loss rate scaled by its quality performance and that is not changed by proposals in this rule.
- For an affected ACO eligible to receive a health equity adjustment as provided for by policies proposed in this rule, the bonus points would be calculated and awarded according to those policies if finalized. If the ACO's health equity-adjusted quality score is higher than the quality performance score assigned to it per existing policy, the equity-adjusted score would replace the policy-based score. In practicality, the ACO would qualify for the maximum savings rate with or without the bonus points.
- For an affected ACO on the ENHANCED track and liable for shared losses, receiving bonus points could potentially produce an equity-adjusted performance score that would reduce losses more than would the performance score assigned per policy. The equity-adjusted score would be used to calculate the shared loss reductions.
- An ACO affected by extreme and uncontrollable circumstances that fails to report quality data via the APP, or whose data do not meet completeness or case minimum requirements, by definition would not meet the proposed eligibility criteria for receiving equity bonus points. Therefore, the affected ACO would be assigned its quality score per policy (e.g., 30th percentile across MIPS quality measures for PY 2023).

g. Summary of Proposals

CMS provides its quality standard and reporting proposals arranged by first applicable performance year in narrative form in section III.G.4.(b)(9) and in tabular form as Table 51 (reproduced earlier in this summary). CMS lists its proposals with their associated regulation text changes in section III.G.4.b(7)(h). **The agency also emphasizes several of its requests for comment on specific aspects of its proposals: (1) the measure performance scaler and its associated value assignments, (2) capping the health equity bonus points at 10, (3) setting a minimum ADI proportion above the 85th percentile to be eligible for bonus points, and (4) the alternative methodologies considered for determining the underserved multiplier (e.g., use of the LIS as an underserved indicator variable).**

h. Shared Savings Program Quality Measure and Benchmark Changes

In Table 52, CMS lists the required measures as finalized for PY 2022 for both the CMS Web Interface and APP measure set quality reporting options. For PY 2023, the measures for both options are largely unchanged from those adopted for PY 2022. The Web Interface option will no longer be available starting with PY 2025.

(1) Web Interface Reporting

CMS notes that measure Q110 *Preventive Care and Screening: Influenza Immunization* is being proposed for removal from the MIPS Quality Measure Inventory for all uses except in the Shared Savings Program beginning with PY 2023 (see Appendix 1 Table Group CC for the detailed rationale for removal). The measure will be retained in the Web Interface set for continued use in the Shared Savings Program. Additionally, changes are proposed to all measures in the Web Interface set including Q110. Many changes are technical specification revisions and others

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increase alignment between eCQMs and their corresponding MIPS CQMs. All of the measures, the changes, and rationales for change are described in detail in Appendix 1 Table Group E.

(2) Web Interface Benchmarks

CMS proposes to create benchmarks according to previously established Shared Savings Program policies (found at §425.502(b)) for the measures in the Web Interface set for PYs 2022 through 2024. CMS would accomplish this change by adding new paragraph (a)(6) to §425.512, where the quality performance standard is codified for years beginning on or after January 1, 2021. When use of this measure set by ACOs was extended beyond PY 2021 during CY 2022 PFS rulemaking, CMS inadvertently failed to update the measure benchmarks. Proposing benchmarks now for PY 2022 represents retroactive application of a substantive change and CMS proposes to do so by invoking its authority under section §1871(e)(1)(A) of the Act to apply such changes when failing to do so would not be in the public interest. CMS presents a detailed rationale for using its authority in section III.G.4.c(2) of the rule.

CMS further proposes to score 2 Web Interface measures using flat percentage benchmarks for PY 2022: *Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention* (Q226) and *Preventive Care and Screening: Screening for Depression and Follow-up Plan* (Q134). By so doing, CMS addresses issues of having incorrectly stated during CY 2022 rulemaking that a benchmark would not be created for Q226 and having newly determined that sufficient historical data for benchmarking is lacking for Q134. Policies for applying flat percentage benchmarks are found at §425.502(b)(2). CMS would again apply its authority to make retroactive changes. In support of retroactive change, CMS notes that the proposed changes, if finalized, would increase the number of Web Interface measures on which ACOs could be scored and thereby contribute to their quality performance scores as well as potentially allow them to achieve shared savings. CMS anticipates applying flat percentage benchmarks again for PY 2023 for these 2 measures.

(3) APP Measure Reporting

CMS proposes to retitle the measure *Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS* finalized for PY 2023 to *Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions* and to designate it as quality measure ID# 484. The change is proposed beginning with PY 2023 in order to align measure nomenclature between the Shared Savings Program and the MIPS Quality Inventory. This measure as proposed and the others that would constitute the program's APP measure set for PY 2023 are shown in Table 53 of the rule and below. The set is otherwise unchanged from PY 2022. In the table CMS also identifies the APP outcome measures within the set to facilitate their use to satisfy certain proposed options of the Shared Savings Program's quality performance standard and alternative quality performance standard (shown in Table 51 earlier in the rule and above in this summary).

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Table 53: Proposed APP Measure Set for eCQM/MIPS CQM Reporting for Performance Year 2023 (reproduced in part from the rule)			
Measure ID #	**Measure Title**	**Measure Type**	**Performance Standard Outcome Measure?***
Q321	CAHPS for MIPS Survey	Patient-Reported Outcome	No
Q479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Outcome	Yes
Q484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Outcome	Yes
Q001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	Intermediate Outcome	Yes
Q134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	Process	No
Q236	Controlling High Blood Pressure	Intermediate Outcome	Yes
* Yes = can be used to meet "outcome" provisions of the Shared Savings Program's quality performance standard or alternative quality performance standard			

i. Clarifying Unweighted MIPS Score Utilization for Quality Standard Determinations

When reporting quality data using the APP measure set, Shared Savings Program ACOs must achieve specified quality score percentiles on eCQMs/MIPS CQMs in order to meet the Program's Quality performance standard and receive shared savings (e.g., 40th percentile for PY 2025 and subsequent years). During PY 2022 rulemaking, CMS began providing historical data for the relevant score percentiles to guide ACOs when comparing their anticipated quality scores to the percentiles required for earning shared savings. CMS provides historical values because current year percentiles are not calculable until all MIPS data have been submitted (after the first quarter of the following year).

CMS has discovered that the historical reference values published during CY 2022 rulemaking (86 FR 39274 and 86 FR 65271) were erroneously determined using a weighted rather than unweighted distribution of MIPS Quality performance category scores. The unweighted distribution had been used in prior years' calculations, and CMS clarifies that the unweighted distribution will continue to be used in future years. In Table 54 of the rule, CMS provides corrected percentile values for PYs 2018 and 2019 along with properly calculated values for PY 2020. The table is reproduced below with the addition of the erroneously calculated, previously published values.

Table 54: Historical Unweighted MIPS Quality Performance Category Scores (modified by HPA to include previously published values)				
PY	**30th percentile**		**40th percentile**	
	Incorrect	**Correct**	**Incorrect**	**Correct**
2018	83.9	59.30	93.3	70.80
2019	87.9	58.00	95.7	70.82
2020	No value published	63.90	No value published	75.59

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j. Reopening Initial Determinations of ACO Financial Performance

Timelines for the Shared Savings Program's financial reconciliation process and for the MIPS targeted review process are not fully aligned. CMS generally releases reconciliation reports in August for the prior PY that include determinations of whether ACOs have met the quality performance standard and are eligible for shared savings or responsible for shared losses. CMS states that MIPS performance feedback reports are issued "typically in the summer". The targeted review period during which an ACO can question its quality category score results opens with receipt of its feedback report and lasts for 60 days, so that all targeted reviews may not be completed until as late as November. As a result of timeline mismatch, an ACO might not discover nor CMS be made aware of MIPS feedback errors that affect ACO performance results until well after an ACO's initial financial determination has been made and during which time CMS may have issued a demand letter to the ACO for recoupment of shared losses.

CMS now describes a standardized approach to reopening ACO financial determinations for good cause – errors resulting from timeline mismatch – that is under consideration by the agency. Under this approach:

1) CMS would not set thresholds for error magnitude or number of ACOs affected that could trigger reopening;
2) Upon learning of a MIPS quality score error, CMS would exercise its reopening discretion (see §425.502) to correct errors affecting shared savings eligibility determination or shared savings/loss amounts; and
3) Once having found good cause to make a correction(s), CMS would apply shared savings or loss changes to the ACO's financial reconciliation during the following year.

CMS notes that the reopening process would not defer the obligation of an ACO that has received a demand notice to repay those shared losses within 90 days of being notified. Any over- or underpayments would be addressed in the following year's financial reconciliation.

CMS seeks comment on this clarification of when it would exercise its discretion to reopen for good cause when either an initial determination or a final agency determination regarding an ACO's financial performance needs to be corrected as a result of any corrections made to MIPS Quality performance category scores that affect the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO.

k. Request for Information (RFI): Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health Measures and Future Measure Development

CMS seeks comment on the potential future inclusion of two new measures in the APP Measure set if they first are adopted into the MIPS Measure Inventory for use in the traditional MIPS program.

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Screening for Social Drivers of Health

This process measure is being proposed elsewhere in this rule for inclusion within all of the inventory's specialty measure sets for performance year 2023/payment year 2025 of the traditional MIPS program. It is being specified as a CQM but not as an eCQM at this time. The measure assesses the percentage of adult beneficiaries in a provider's practice who are screened for 5 health-related social needs (HRSNs): food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety. The Measure Applications Partnership (MAP) conditionally supported this measure for rulemaking, and it is not yet endorsed by the National Quality Forum (NQF). The measure as adapted for use in the acute care hospital setting also has been proposed for adoption into the Hospital Inpatient Quality Reporting (HIQR) program for voluntary reporting for CY 2023/FY 2025 payment and mandatory reporting beginning with CY 2024/FY 2026 payment.

Screen Positive Rate for Social Drivers of Health

This structural measure is not being proposed at this time for addition to the MIPS inventory. It has been specified as a CQM but not as an eCQM at this time. It assesses the percentage of screened patients who were screen-positive for each of the 5 HRSNs, so that 5 distinct rates are calculated. The Measure Applications Partnership (MAP) conditionally supported this measure for rulemaking, and it is not yet endorsed by the National Quality Forum (NQF). The measure as adapted for use in the acute care hospital setting also has been proposed for adoption into the Hospital Inpatient Quality Reporting (HIQR) program for voluntary reporting for CY 2023/FY 2025 payment and mandatory reporting beginning with CY 2024/FY 2026 payment.

Besides feedback about adding the two measures described above to the APP measure set for use in the Shared Savings Program, CMS asks additional questions about the measures, listed below.

- How to best implement the measures and how they could further drive health equity and health outcomes under the Shared Savings Program?
- What are the possible barriers to implementation of the measures in the Shared Savings Program?
- What impact would the implementation of these measures in the Shared Savings Program have on the quality of care provided for underserved populations?
- What type of flexibility with respect to the social screening tools should be considered should the measures be implemented? While supporting flexibility, how can CMS advance the use of standardized, coded health data within screening tools?
- Should the measures, if implemented in the future, be considered pay-for-reporting measures?

CMS notes that elsewhere in this rule advance investment payments (prepaid shared savings) are being proposed for Shared Savings Program ACOs that meet specified criteria. One of the

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proposed acceptable uses of the payments would be to support strategies to address patient challenges related to social determinants of health.

L. Request for Information (RFI): Addition of New CAHPS for MIPS Survey Questions

CMS poses questions about several potential changes to the current CAHPS for MIPS survey. Shared Savings Program ACOs must administer the survey in order to meet the program's quality performance standard and to be eligible for shared savings.

Personal Experience with Discrimination During Healthcare Delivery

CMS cites study data from 2019 suggesting that roughly 20 percent of adults have experienced discrimination in the health care system. To further explore this topic, CMS asks for input on adding the question and response choices below to the CAHPS for MIPS survey.

> Question: "In the last 6 months, did anyone from a clinic, emergency room, or doctor's office where you got care treat you in an unfair or insensitive way because of any of the following things about you?"
> Responses: Health condition, disability, age, culture, sex (including sexual orientation and gender identity), and income.

This question is being tested in the Medicare Advantage program. Results from that testing will inform the agency's decision making about proposing this CAHPS change through rulemaking.

Price Transparency

CMS seeks feedback on future CAHPS for MIPS survey questions dealing with price transparency and views such questions as consistent with the goals of the No Surprises Act.[13] The survey currently asks "In the last 6 months, did you and anyone on your health care team talk about how much your prescription medicines cost?" CMS is considering adding a more general question such as whether the patient had talked with anyone on their health care team about the cost of health care services and equipment.

Survey Modification for Specialty Group Application

CMS requests input on two options for modifying the CAHPS for MIPS survey to make it more broadly applicable to specialty groups in addition to primary care groups: (1) shortening the survey by removing items relevant only to primary care providers and using the shorter survey with all practitioner groups, or (2) creating a separate shorter survey version for use in assessing specialist care and maintaining the existing longer survey for use with primary care groups.

[13] Title I, Division BB of the Consolidated Appropriations Act, 2021, Pub. L. 116-133.

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5. Financial Methodology

a. Overview

In this section of the proposed rule, CMS is proposing modifications to the financial methodologies under the Shared Savings Program. It states that its proposals are aimed at encouraging sustained participation by ACOs in the program and removing barriers for ACOs serving medically complex and low-income populations. Specifically, CMS is proposing to:

- Incorporate a prospective, external factor in growth rates used to update the historical benchmark
- Adjust ACO benchmarks to account for prior savings
- Reduce the impact of the negative regional adjustment
- Calculate county FFS expenditures to reflect differences in prospective assignment and preliminary prospective assignment with retrospective reconciliation
- Improve the risk adjustment methodology to better account for medically complex, high-cost beneficiaries and guard against coding initiatives
- Increase opportunities for low revenue ACOs to share in savings

The proposed rule also discusses alternatives to some of the combinations it proposed. It discusses ongoing concerns about the impact of the PHE for COVID-19 on ACOs' expenditures. It proposes to exclude from the determination of Medicare Parts A and B expenditures for purposes of calculations under the Shared Savings Program a proposed new supplemental payment for Indian Health Service and Tribal hospitals and hospitals located in Puerto Rico. It concludes with a discussion of modifications to 42 CFR part 425, subpart G to incorporate the related proposed changes.

b. Statutory and Regulatory Background on Establishing and Updating the Benchmark and Determining Savings

Section 1899(d)(1)(B)(i) of the Act specifies that, in each year of the agreement period, an ACO is eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark under section 1899(d)(1)(B)(ii) of the Act. Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established and updated under the Shared Savings Program. Section 1899(i)(3) of the Act grants the Secretary the authority to use other payment models, including payment models that would use alternative benchmarking and savings determination methodologies, if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under the Medicare program and that the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model.

The rules governing the benchmarking calculations and determination of shared savings and losses are set forth in the regulations at 42 CFR part 425, subpart G. In the November 2011 final rule establishing the Shared Savings Program, CMS adopted policies for establishing, updating,

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and resetting the benchmark at §425.602. The Shared Savings Program's regulations have since evolved to include different benchmarking methodologies, including modifications to §425.602, and the addition of separate benchmarking policies for ACOs entering a second or subsequent agreement period at §425.603. Benchmarking policies applicable to all ACOs in agreement periods beginning on July 1, 2019, and in subsequent years, are specified in §425.601. Calculations related to determination of shared savings and shared losses are specified in §425.605 for ACOs participating under the BASIC track, and §425.610 for ACOs participating under the ENHANCED track (formerly referred to as Track 3).

In the June 2015 final rule, CMS established Track 3, constituting the program's highest level of risk and potential reward (80 FR 32771 through 32781). In the December 2018 final rule, CMS renamed Track 3 the ENHANCED track (see, for example, 83 FR 67841), and established the BASIC track, which includes a glide path with five Levels (A through E) (83 FR 67841 through 67857). The BASIC track's glide path allows eligible ACOs to begin under a one-sided model and incrementally advance to higher levels of risk and reward.

In the May 8, 2020, COVID-19 IFC (85 FR 27578 through 27582), CMS established adjustments to benchmark and performance year expenditure calculations to address the COVID-19 pandemic as specified under §425.611. In the 2021 PFS final rule (85 FR 84771 through 84785), CMS summarized and responded to public comments received on these adjustments, and finalized the regulation at §425.611 with modifications.

Details on the Shared Savings Program's financial methodology and policies to address the impact of COVID-19 are included in Specifications documents.[14]

c. Strengthening Participation by Reducing the Effect of ACO Performance on Historical Benchmarks, Addressing Market Penetration, and Strengthening Incentives for ACOs Serving Medically Complex and High Cost of Care Populations.

(1) Regulatory Background

To establish an ACO's historical benchmark for an agreement period, CMS uses ACO historical expenditures for beneficiaries that would have been assigned to the ACO in the 3 most recent years prior to the start of the agreement period. As the statute requires the use of historical expenditures to establish an ACO's benchmark, the per capita costs for each benchmark year must be trended forward to current year dollars and then a weighted average is used to obtain the ACO's historical benchmark. Section 1899(d)(1)(B)(ii) of the Act also requires that the benchmark shall be updated by the projected absolute amount of growth in national per capita

[14] See Shared Savings and Losses and Assignment Methodology Specifications Version 10 (cms.gov)

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expenditures for Parts A and B services under the original Medicare FFS program. Therefore, in the November 2011 final rule establishing the Shared Savings Program, CMS adopted policies for trending forward expenditures for benchmark year (BY) 1 and BY2 to BY3 dollars (76 FR 67924 and 67925), and for updating the benchmark for each performance year during the ACO's agreement period (76 FR 67925 through 67927).
Over the 10 years since the Shared Savings Program was first established, CMS has used a variety of approaches for determining the trend and update factors to make an ACO's cost target more independent of its own expenditures, including using factors based on national expenditures, regional expenditures, or both.

In the November 2011 final rule establishing the Shared Savings Program, CMS adopted trend and update factor policies at §425.602 based on national FFS expenditures (76 FR 67924 through 67927). It finalized use of a national growth rate in Medicare Parts A and B expenditures for FFS beneficiaries for trending forward BY1 and BY2 to BY3 dollars. It also finalized use of a flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the Medicare FFS program to update the benchmark for each performance year of the agreement period.

In the June 2015 final rule, CMS adopted policies for resetting the benchmark for ACOs entering a second agreement period in 2016 at §425.603(b) (80 FR 32786 through 32796). These policies addressed concerns about the use of an ACO's prior performance years as benchmark years in second and subsequent agreement periods by weighting each benchmark year equally and incorporating an adjustment to account for the average per capita amount of savings generated during the ACO's prior agreement period. CMS refers to this adjustment as a "prior savings adjustment." This adjustment applied only to ACOs entering a second agreement period beginning in 2016 because it subsequently finalized an alternative methodology incorporating factors based on regional FFS expenditures to establish, adjust and update the benchmark for ACOs beginning a second or subsequent agreement period in 2017 and later years.

In the June 2016 final rule (81 FR 37953 through 37991), CMS modified the benchmarking methodology to finalize an approach that incorporated factors based on regional FFS expenditures when resetting (or rebasing) and updating ACO historical benchmarks, as specified in §425.603(c) through (f). It replaced the national trend factor used in the rebasing methodology with a methodology incorporating regional trend factors. This revised rebasing methodology applied beginning in 2017 to determine rebased historical benchmarks for ACOs renewing for a second or subsequent agreement period under the Shared Saving Program.

In the December 2018 final rule (83 FR 68005 through 68030), CMS adopted policies at §425.601 that expanded the use of regional factors in establishing, adjusting, and resetting historical benchmarks to all ACOs, including ACOs in a first agreement period, for agreement periods beginning on July 1, 2019, or in subsequent years. These policies sought to address concerns about ACOs influencing their own regional trends by using a blend of national and regional trend factors to trend forward BY1 and BY2 to BY3 when determining the historical benchmark under §425.601(a)(5) and a blend of national and regional update factors to update the historical benchmark to the performance year under §425.601(b) (83 FR 68024 through

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68030). CMS also established a symmetrical cap on the regional adjustment to the historical benchmark equal to positive or negative 5 percent of the national per capita FFS expenditures for assignable beneficiaries for each enrollment type. CMS also modified the schedule of weights used to phase in the regional adjustment at §425.601(f), to reduce the maximum weight from 70 to 50 percent for all ACOs and to slow the phase-in of weights for ACOs with higher spending than their regional service area.

(2) Overview of Considerations for Modification to the Benchmarking Methodology

CMS proposes a combination of policies to ensure a robust benchmarking methodology that would reduce the effect of ACO performance on ACO historical benchmarks and increase options for ACOs caring for high-risk populations. Specifically, CMS proposes to 1) modify the methodology for updating the historical benchmark to incorporate a prospective, external factor; 2) incorporate a prior savings adjustment in historical benchmarks for renewing and re-entering ACOs; and 3) reduce the impact of the negative regional adjustment. It believes these proposed modifications could serve as "stepping stones" to a longer-term approach to the benchmarking methodology, and they are designed to be consistent with the potential approach for incorporating a methodology for administratively set benchmarks, which is described in the related RFI.

These and the other proposed changes to the Shared Savings Program's benchmarking methodology within this proposed rule, would be applicable to establishing, updating, and adjusting the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.

(3) Incorporating a Prospective, External Factor in Growth Rates Used to Update the Historical Benchmark

CMS proposes to incorporate a prospectively projected administrative growth factor, a variant of the United States Per Capita Cost (USPCC) referred to in the proposed rule as the Accountable Care Prospective Trend (ACPT), into a three-way blend with national and regional growth rates to update an ACO's historical benchmark for each PY in the ACO's agreement period. CMS believes that incorporating this prospective trend in the update to the benchmark would insulate a portion of the annual update from any savings occurring as a result of the actions of ACOs participating in the Shared Savings Program and address the impact of increasing market penetration by ACOs in a regional service area on the existing blended national-regional growth factor.

CMS would calculate a three-way blend as the weighted average of the ACPT (one-third) and the existing national-regional blend (two-thirds) for use in updating an ACO's historical benchmark between benchmark year (BY) 3 and the PY. The ACPT would be projected by the CMS Office of the Actuary (OACT) and would be a modification of the existing FFS USPCC growth trend projections used annually for establishing Medicare Advantage rates, excluding indirect medical education (IME), disproportionate share hospital (DSH) payments, uncompensated care payments, and the proposed new supplemental payment for Indian Health Service (IHS)/Tribal Hospitals and hospitals located in Puerto Rico, and including payments associated with hospice claims to be consistent with Shared Savings Program's expenditure

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calculations. CMS proposes to set the ACPT growth factors for the ACO's entire 5-year agreement period near the start of the agreement period. The ACPT factors would remain unchanged throughout the ACO's agreement period, providing a degree of certainty to ACOs.

CMS considered whether the ACPT component of the blend should express projected growth on a relative basis (as the current two-way national-regional blend operates) or on an absolute (flat) dollar basis. It anticipates that the risk-adjusted flat dollar approach will be more beneficial to ACOs. The flat dollar amounts would be risk adjusted to account for differences in severity and case mix between the ACO's assigned beneficiaries and the national assignable FFS population for each Medicare enrollment type. It is not proposing to adjust the ACPT flat dollar amounts for geographic differences in costs or prices, as it believes that doing so could inadvertently reward higher spending, less efficient ACOs with a higher market share in their regional service area.

CMS illustrates in the proposed rule the four steps it would use to set the annualized growth rate(s) and calculate the ACPT flat dollar amounts(s) that would be included in the three-way blend.

Step 1: Calculate annualized growth rate(s) for agreement period

For step 1, OACT would calculate one or more annualized growth rates for the ESRD population (the ESRD ACPT) and one or more annualized growth rates for the aged/disabled population. These annualized growth rate may either be calculated as a uniform annualized projected rate of growth or as a two or more annualized growth rates over each of the 5 performance years of the 5-year agreement period if CMS determines that a uniform annualized projected rate of growth does not reasonably fit the anticipated growth curve.

Step 2: Express the growth rate(s) for each performance year as flat dollar amounts (the ACPT).

For step 2, CMS would multiply BY3 truncated national per capita FFS expenditures calculated by OACT for the assignable FFS population for a given enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries), by the applicable growth rate to calculate the flat dollar amount of growth for each performance year. Thus, for example, if the truncated national assignable per capita expenditures for a given enrollment type was $13,000, and the projected growth rate for that enrollment type in that year is 5 percent per year, the flat dollar amounts would be:

PY1 flat dollar amount = $13,000 x (1.050 – 1) = $650, and PY5 flat dollar amount = $13,000 x (1.276 – 1) = $3,588251

Step 3: Risk adjust the flat dollar amounts.

In step 3, CMS would multiply the flat dollar amounts for each performance year, for each enrollment type, by the ACO's mean BY3 prospective Hierarchical Condition Category (HCC) risk score for that enrollment type. The risk score used would first be renormalized by dividing by the national mean risk score for the assignable FFS population for that enrollment type identified for the calendar year corresponding to BY3. Risk adjusting the flat dollar amounts would allow for a higher update for ACOs serving a population that is more medically complex

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than the national average. If the ACO's BY3 risk score was 1.025, the risk adjusted flat dollar amounts would be:

PY1 flat dollar amount = $650 x 1.025 = $666, and PY5 flat dollar amount = $3,588 x 1.025 =$3,678

Step 4: Re-express risk adjusted flat dollar amounts as relative factors.

The fourth and final step before calculating the three-way blended update factor would be to re-express the risk adjusted flat dollar amount for each enrollment type on a relative basis such that it can be combined in a weighted average with the current two-way blend. CMS would divide the risk adjusted flat dollar amounts computed in Step 3 for a given enrollment type by the ACO's historical benchmark expenditures for that enrollment type. If the historical benchmark expenditures for the enrollment type were $12,000, the final ACPT portion of the blended update factors for this enrollment type would be:

PY1 final ACPT portion of the blended update factor = ($666 / $12,000) + 1 = 1.056, and PY5 final ACPT portion of the blended update factor = ($3,678 / $12,000) + 1 = 1.306

The values in this step would then be combined with the two-way blend to compute the three-way blended update factor. The ACPT would constitute one-third of the total blend, while the remaining two-thirds would consist of the existing two-way blend.

CMS provides an example that results in a higher benchmark which increases the ACO's potential for shared savings and reduces the potential for shared losses, if applicable. It also notes, however, that incorporating the ACPT into a three-way blended update factor could have the potential for mixed effects.

Implementation of a Guardrail to provide protection for ACOs from larger share losses. To address this issue, CMS proposes a "guardrail" to provide protection for ACOs from larger shared losses (or potentially from the negative implications of financial monitoring) based on an updated flexibility to reduce the impact the prospectively determined ACPT portion of the three-way blend if unforeseen circumstances occur during an ACO's agreement period.

CMS would recalculate the ACO's updated benchmark using the national-regional blended factor (two-way blend). If the ACO generates savings using the two-way blend (but not in the three-way blend), the ACO would neither be responsible for shared losses nor eligible for shared savings for the applicable performance year.

It also acknowledges, however that a variety of circumstances could cause actual expenditure trends to significantly deviate from the projections. CMS would retain discretion to decrease the weight applied to the ACPT in the three-way blend (i.e., different than the one-third, absent unforeseen circumstances). It proposes that it would have sole discretion to determine whether unforeseen circumstances exist that would warrant adjustments to these weights.

Impact of Using a Three-Way Blend on Benchmarks. CMS simulated the potential impact of the three-way blend rather than two-way blend and found that, on average, ACOs were better off

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over the course of the 5-year agreement period and the ACOs benchmark on average increased more. Specifically, CMS observed that, on average, over the 5-year period used in its modeling, about 65 percent of ACOs operating in markets with high Shared Savings Program had a larger benchmark increase under the three-way blend compared with the two-way blend. This approach also benefited ACOs with high percentages of dual-eligibles, disabled populations, and ACOs operating in rural areas.

CMS seeks comment on its proposal to use a three-way blend that incorporates the ACPT to update an ACO's historical benchmark for agreement periods beginning on January 1, 2024, and in subsequent years. It also seeks comment on the specific elements of this approach, including its proposal to calculate the ACPT on a risk adjusted flat dollar basis, to institute a guardrail to protect ACOs, and to retain discretion to adjust the weight applied to the ACPT and the two-way blend in the event of unforeseen circumstances.

(4) Adjusting ACO Benchmarks to Account for Prior Savings

CMS proposes to incorporate an adjustment for prior savings that would apply in the establishment of benchmarks for renewing ACOs and re-entering ACOs, that were reconciled for one or more performance years in the three years preceding the start of their agreement period. It believes that such an adjustment would help to mitigate the rebasing ratchet effect on an ACO's benchmark. Furthermore, CMS believes that returning dollar value to benchmarks through a prior savings adjustment could help address an ACO's effects on expenditures in its regional service area. CMS would adjust an ACO's benchmark based on the higher of either the prior savings adjustment or the ACO's positive regional adjustment. It would also use a prior savings adjustment to offset negative regional adjustments for ACOs that are higher spending compared to their regional service area. Overall, CMS believes that this proposal would help ensure that high performing ACOs have incentives to remain in the program for the long-term.

CMS proposes to use the following steps to calculate the prior savings adjustment:

Step 1: *Calculate total per capita savings or losses in each performance year that constitutes a benchmark year for the current agreement period.* For each performance year CMS would determine an average per capita amount reflecting the quotient of the ACO's total updated benchmark expenditures minus total performance year expenditures divided by performance year assigned beneficiary person years. CMS would apply certain requirements in determining the amount of per capita savings or losses for each performance year. For example, the per capita savings or losses would be set to zero for a performance year if the ACO was not reconciled for the performance year.

Step 2: Calculate average per capita savings. Calculate an average per capita amount of savings by taking a simple average of the values for each of the 3 performance years as determined in Step 1, including values of zero, if applicable. CMS would use the average per capita amount of savings to determine the ACO's eligibility for the prior savings adjustment as follows:

- If the average per capita value is less than or equal to zero, the ACO would not be eligible for a prior savings adjustment. The ACO would receive the regional adjustment to its benchmark.

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- If the average per capita value is positive, the ACO would be eligible for a prior savings adjustment.

Step 3: Apply a proration factor to the per capita savings calculated in Step 2. This would be equal to the ratio of the average person years for the 3 performance years that immediately precede the start of the ACO's current agreement period (regardless of whether these 3 performance years fall in one or more prior agreement periods), and the average person years in benchmark years for the ACO's current agreement period, capped at 1. This ratio would be redetermined for each performance year during the agreement period in the event of any changes to the number of average person years in the benchmark years as a result of changes to the ACO's certified ACO participant list, a change to the ACO's beneficiary assignment methodology selection under §425.400(a)(4)(ii), or changes to the beneficiary assignment methodology.

Step 4: Determine final adjustment to benchmark. Compare the pro-rated positive average per capita savings from Step 3 with the ACO's regional adjustment expressed as a single per capita value by taking a person-year weighted average of the Medicare enrollment type-specific regional adjustment values. As detailed in the proposed rule, CMS would adjust an ACO's benchmark based on the higher of either the prior savings adjustment or the ACO's positive regional adjustment. It would also use a prior savings adjustment to offset negative regional adjustments for ACOs that are higher spending compared to their regional service area.

Tables 55 through 58 present hypothetical examples to demonstrate how the adjustment for prior savings would work in practice. In its simulations using 2020 data, CMS states that no ACOs would receive a lower benchmark and that about 22 percent of all ACOs would receive a higher benchmark under this policy. Among ACOs that receive a higher benchmark, the average net effect on per capita benchmark expenditures would be about $130 measured across each of the four enrollment types.

CMS seeks comment on its proposal to adjust the ACO's historical benchmark for savings generated in the ACO's prior agreement period.

(5) Reducing the Impact of the Negative Regional Adjustment

CMS proposes to institute two policy changes designed to limit the impact of negative regional adjustments on ACO historical benchmarks and further incentivize program participation among ACOs serving high cost beneficiaries. It proposes to reduce the cap on negative regional adjustments from negative 5 percent of national per capita expenditures for Parts A and B services under the original Medicare FFS program in BY3 for assignable beneficiaries to negative 1.5 percent. It also proposes that after the cap is applied to the regional adjustment, to gradually decrease the negative regional adjustment amount as an ACO's proportion of dual eligible Medicare and Medicaid beneficiaries increases or its weighted—average prospective HCC risk score increases.

For negative regional adjustments, CMS also proposes to apply an offset factor based on the following: [A] the ACO's overall proportion of BY3 assigned beneficiaries that are dually eligible for Medicare and Medicaid (including dually eligible ESRD, disabled, and aged

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beneficiaries) and [B] the ACO's weighted average prospective HCC risk score for BY3 taken across the four Medicare enrollment types. Specifically, the offset factor would be calculated as:

Offset factor = [A] + ([B] – 1)

This offset factor would be applied to negative regional adjustments after the negative 1.5 percent cap is applied. The offset factor would be subject to a minimum of zero and a maximum of one. It would be calculated as:

Final regional adjustment = Negative regional adjustment x (1 – Offset factor)

The higher an ACO's proportion of dual eligible beneficiaries or the higher its risk score, the larger the offset factor would be and the larger the reduction to the overall negative regional adjustment. If the offset factor is equal to the maximum value of one, the ACO would not receive a negative regional adjustment (that is, the negative weighted average regional adjustment would be fully offset). If the offset factor is equal to the minimum value of zero, the ACO would receive no benefit from the offset factor.

Table 61 in the proposed rule shows a hypothetical example of how a proposed offset factor applied to negative regional adjustments. In its simulations of this proposed policy, CMS found that for ACOs that had a negative regional adjustment under the current policy such an adjustment would have been reduced or eliminated under the proposed policy. It also benefits ACOs that had positive weighted regional adjustment under the current policy but that had at least one enrollment type with a negative regional adjustment. CMS believes that applying the lower cap and the offset factor at the enrollment type level is more straightforward and will have the opportunity to benefit ACOs that may be serving high risk populations in at least one, but not all Medicare enrollment types.

CMS seeks comment on these proposed changes to the calculation of the regional adjustment for agreement periods beginning on January 1, 2024, and in subsequent years.

(6) Alternatives Options for Addressing Concerns about the Effect of an ACO's Assigned Beneficiaries on Regional FFS Expenditures in Establishing, Adjusting, Updating, and Resetting the ACO's Historical Benchmark

CMS also considered alternative options to the three proposals described above in section III.G.5.c.(3) through (5) that would more directly reduce the effect of the ACO's own beneficiaries on its regional FFS expenditures: (1) removing an ACO's assigned beneficiaries from the assignable beneficiary population used in regional expenditure calculations; and (2) expanding the definition of the ACO's regional service area to use a larger geographic area to determine regional FFS expenditures. These related approaches were policies CMS sought comment in the 2022 PFS proposed rule.

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Alternative 1: Removing an ACO's assigned beneficiaries from the assignable beneficiary population used in regional expenditure calculations

Under this alternative, CMS would exclude an ACO's assigned beneficiaries from the population of assignable beneficiaries in the ACO's regional service area used to determine the regional FFS expenditures used in all benchmarking calculations including trending and updating the benchmark and calculating the regional adjustment. To remove an ACO's assigned beneficiaries from the regional expenditure calculation, CMS would use the mathematical approach described in the CY 2022 PFS proposed rule (86 FR 39292 and 39293), which is premised on per capita risk adjusted FFS expenditures for all assignable beneficiaries in an ACO's regional service area (a) can be interpreted as a weighted average of per capita risk adjusted FFS expenditures for the ACO's assigned beneficiaries (b) and per capita risk adjusted FFS expenditures for assignable beneficiaries in the region who are not assigned to the ACO (c), where the weight on (b) is the ACO's regional market share and the weight on (c) is one minus the ACO's regional market share. Shown as an equation this is:

(a) = [(b) x (ACO's regional market share)] + [(c) x (1 – ACO's regional market share)].

Thus, to remove the ACO's assigned beneficiaries from the regional expenditure calculation, CMS would insert the applicable values for (a), (b), and regional market share (all data elements already computed under the current benchmarking methodology) into the above equation and solve for (c) by rearranging the equation as follows:

(c) = {(a) – [(b) x (ACO's regional market share)]} / (1 – ACO's regional market share).

CMS believes this approach would pose relatively limited operational burden and many commenters responding to its comment solicitation stated that this solution could work well. It remains concerned, however, that such an approach to remove an ACO's assigned beneficiaries from the assignable population could incentivize ACOs to "cherry-pick" healthier, lower-cost patients and could unfairly penalize ACOs that specialize in more medically complex, higher-cost patients, running counter to one of the core dynamics it seeks to address (86 FR 65300 and 65301). CMS is also concerned that this approach would incentivize market consolidation.

CMS states that if it were to finalize this option, it would potentially need to adjust the weights currently used in calculating the regional adjustment to the historical benchmark. This could occur, for example, if an ACO were serving an assigned population that is markedly healthier than other assignable beneficiaries in the ACO's regional service area. CMS is worried that this could potentially lead to a dramatic increase in program costs as higher regional adjustments could translate into higher shared savings payments.

Alternative 2: Expanding the regional service area

The second alternative CMS considered in place of the package of policies that it is proposing would seek to reduce an ACO's influence on expenditures in its regional service area by expanding the ACO's regional service area. CMS notes that while it did not outline a specific approach in the 2022 PFS proposed rule, it sought comment on basing regional expenditure

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calculations on larger geographic areas, such as using State-level data or Core-Based Statistical Area (CBSA)-level data, or a combination of data for these larger geographic areas and county-level data (such as blended county/State expenditures).

MedPAC commented to CMS favoring altering the calculation of regional spending by extending the ACO's regional service area to a larger market area (for example, CBSAs, health service areas, or hospital referral regions) in lieu of removing ACO assigned beneficiaries from the calculation of regional FFS expenditures, noting that expanding an ACO's regional service area would help to reduce an ACO's influence on its regional benchmark calculation without explicitly favoring certain categories of ACOs (for example, historically low spending ACOs). Other commenters also supported expanding the regional service area for the purposes of calculating regional FFS expenditures in cases where ACO market penetration is high – some suggested a threshold of 50 percent.

CMS believes that adopting only this second alternative to expand the regional service area would reduce the impact of an ACO's own expenditures on its regional expenditures without introducing incentives for favorable patient selection or concerns about increased volatility that may result from the first alternative of excluding an ACO's assigned beneficiaries from the population of assignable beneficiaries used to determine regional FFS expenditures. It does not believe, however, that it would be as effective in countering the "ratchet effect" It believes that its proposal to incorporate the ACPT into the growth rates used to update the benchmark would ensure that a portion of the update will remain unaffected by observed FFS spending. Furthermore, it has concerns that use of a market penetration threshold may drive further market consolidation as ACOs seek to meet such a threshold.

It also notes that if it were to finalize this second alternative or a combined approach, there are a number of operational factors that it would need to address with greater specificity, including, but not limited to: what alternative geographic area it would use, whether it would replace county-level data with data based on an alternate geographic area or use a blend, and, if using a blend, at what threshold it would be triggered, and what weights would be applied when aggregating expenditures across geographic areas.

d. Calculating County FFS Expenditures to Reflect Differences in Prospective Assignment and Preliminary Prospective Assignment with Retrospective Reconciliation

Under the current benchmarking methodology, CMS uses risk adjusted county-level FFS expenditures, determined based on expenditures for assignable beneficiaries identified for the 12-month calendar year corresponding to the relevant benchmark or performance year, to calculate factors based on regional FFS expenditures used in establishing, adjusting, and updating the ACO's historical benchmark. CMS believes this approach creates a systematic bias in the calculations using county-level expenditures that favors ACOs under prospective assignment.

To remove the favorable bias and bring greater precision to the calculation of factors based on regional FFS expenditures, CMS proposes to calculate risk adjusted regional expenditures using county-level values computed using an assignment window that is consistent with an ACO's

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assignment methodology selection for the performance year. That is, for ACOs selecting prospective assignment, CMS would use an assignable population of beneficiaries that is identified based on the offset assignment window (for example, October through September preceding the calendar year) and for ACOs selecting preliminary prospective assignment with retrospective reconciliation it would continue to use an assignable population of beneficiaries that is identified based on the calendar year assignment window. CMS is not proposing to change the way it would compute national factors that require identifying assignable populations.

To facilitate modeling of the proposed changes, CMS is making available, through the Shared Savings Program website the following data files: risk adjusted county-level FFS expenditures for 2018-2020 calculated based on an assignable population identified using an offset assignment window; and data files with ACO-specific information on the applicable assignment methodology for the corresponding years.[15]

e. Improving the Risk Adjustment Methodology to Better Account for Medically Complex, High-Cost Beneficiaries and Guard Against Coding Initiatives

Currently, for ACOs in agreement periods beginning on or after July 1, 2019, CMS uses prospective HCC risk scores to adjust the ACO's historical benchmark at the time of reconciliation for a performance year to account for changes in severity and case mix for the ACO's assigned beneficiary population between BY3 and the performance year, subject to a cap of positive 3 percent for the agreement period (referred to herein as the "3 percent cap").

Currently, the 3 percent cap is applied separately for the population of beneficiaries in each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries). That is, any positive adjustment between BY3 and any performance year in the agreement period cannot be larger than 3 percent for any Medicare enrollment type.

CMS developed several options to address concerns raised by stakeholders including, but not limited to, accounting for higher volatility in prospective HCC risk scores for certain enrollment types due to smaller sample sizes and allowing for higher benchmarks than the current risk adjustment methodology for ACOs that care for larger proportions of beneficiaries in aged/dual eligible, disabled and ESRD enrollment types (which are more frequently subject to the cap on risk score growth currently).

The three options that CMS considered would modify the existing 3 percent cap on risk score growth:

1. Account for all changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year prior to applying the 3 percent cap on positive adjustments resulting from changes in prospective HCC risk scores, and apply the cap in

[15] See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram?redirect=/sharedsavingsprogram/

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aggregate across the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible);

2. Apply the 3 percent cap in aggregate across the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) without first accounting for changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year; and

3. Allow the cap on an ACO's risk score growth to increase by a percentage of the difference between the current 3 percent cap and risk score growth in the ACO's regional service area, where the percentage applied would be equal to 1 minus the ACO's regional market share.

After consideration of the options, CMS is proposing the first option to modify the existing 3 percent cap on positive prospective HCC risk score growth, such that an ACO's aggregate prospective HCC risk score would be subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year plus 3 percentage points. In other words, CMS would calculate a single aggregate value for the cap equal to the dollar-weighted average growth in demographic risk scores across the four enrollment types plus 3 percentage points. CMS would only apply this cap to prospective HCC risk score growth for a particular enrollment type if the aggregate growth in prospective HCC risk scores, calculated as the dollar-weighted average growth in prospective HCC risk scores across the four enrollment types, exceeds the value of the cap.

To implement the new cap, CMS would follow these steps:

Step 1: Determine demographic risk score growth for each Medicare enrollment type.

Demographic risk score growth is measured as the ratio of the ACO's performance year demographic risk score for an enrollment type to the ACO's BY3 demographic risk score for that enrollment type.

Step 2: Calculate the dollar-weighted average demographic risk ratio across the four enrollment types to obtain a single aggregate dollar-weighted average demographic risk ratio. The dollar weight for each enrollment type would be equal to historical benchmark expenditures for that enrollment type divided by the sum of historical benchmark expenditures across all enrollment types. Historical benchmark expenditures for each enrollment type would be calculated as per capita historical benchmark expenditures for that enrollment type multiplied by the ACO's BY3 assigned beneficiary person years for that enrollment type. The aggregate dollar-weighted average demographic risk ratio would be computed by multiplying the risk ratio for each enrollment type by its respective dollar weight and then summing across the four enrollment types.

Step 3: Calculate the sum of the aggregate dollar-weighted average demographic risk ratio from Step 2 and 0.030. This would represent the aggregate cap.

Step 4: Determine prospective HCC risk score growth for each Medicare enrollment type. Prospective HCC risk score growth would be measured as the ratio of the ACO's performance

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year prospective HCC risk score for that enrollment type to the ACO's BY3 prospective HCC risk score for that enrollment type.

Step 5: Calculate the aggregate growth in prospective HCC risk scores. This step requires calculating the dollar-weighted average prospective HCC risk ratio across the four enrollment types to obtain a single aggregate dollar-weighted average prospective HCC risk ratio, using the same dollar weights and the same approach described in Step 2.

Step 6: Determine if the ACO will be subject to the cap. If the ACO's aggregate dollar-weighted average prospective HCC risk ratio determined in Step 5 is less than the aggregate cap determined in Step 3, no cap would apply to the prospective HCC risk ratio for any enrollment type, even if the prospective HCC risk ratio for a given enrollment type is higher than the aggregate cap. If the ACO's aggregate dollar-weighted average prospective HCC risk ratio determined in Step 5 is greater than or equal to the aggregate cap determined in Step 3, proceed to Step 7.

Step 7: Compare the prospective HCC risk ratio for each enrollment type calculated in Step 4 to the aggregate cap determined in Step 3. If the prospective HCC risk ratio for a given enrollment type is greater than the aggregate cap, the prospective HCC risk ratio for that enrollment type would be set equal to the aggregate cap. If the prospective HCC risk ratio for a given enrollment type is less than or equal to the aggregate cap, no cap would apply to the prospective HCC risk ratio for that enrollment type.

The resulting prospective HCC risk ratios would then be multiplied by the ACO's historical benchmark expenditures for the relevant Medicare enrollment type at the time of reconciliation for a performance year to account for changes in severity and case mix for the ACO's assigned beneficiary population between BY3 and the performance year.

Table 63 in the proposed rule provides a numeric example of this proposed methodology for a hypothetical ACO that is determined to be subject to the cap. Table 64 shows an example whether the hypothetical ACO is not subject to the cap.

CMS' modeling suggests that a majority of ACOs that operate in regions with risk score growth in excess of 3 percent for at least one Medicare enrollment type would have had higher updated benchmark under the proposed policy than the current policy.

CMS seeks comment on the proposed changes to the risk adjustment methodology for agreement periods beginning on or after January 1, 2024. CMS also seeks comment on the two alternatives considered. CMS states that it will consider the comments received on these alternative options along with the comments on its proposed changes to the risk adjustment methodology, and may consider adopting one of these alternatives in place of the proposed approach if it concludes that it would better address the concerns with the current risk adjustment methodology.

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f. Increased Opportunities for Low Revenue ACOs to Share in Savings

To ensure that ACOs do not receive shared savings payments due to normal year-to-year variations in Medicare beneficiaries' claims expenditures, CMS is required by statute to specify a Minimum Savings Rate (MSR) that first must be attained before making shared savings payments. CMS reviews the history of changes to various MSRs and tradeoffs associated with setting a higher MSR. For example, a higher MSR would provide greater confidence that the shared savings amounts reflect real quality and efficiency gains, but could also discourage potentially successful ACOs (especially physician-organized ACOs and smaller ACOs in rural areas) from participating.

CMS proposes to apply a new approach to low revenue ACOs entering an agreement period in the BASIC track beginning January 1, 2024, and in subsequent years—including new, renewing, and reentering ACOs, in order to provide incentives both for new ACOs to join the Shared Savings Program and for existing ACOs to remain in the program.[16] ACOs in the BASIC track that do not meet the MSR requirement but that do meet the quality performance standard (or the proposed alternative quality performance standard described earlier) would qualify for a shared savings payment if the following criteria are met:

- The ACO has average per capita Medicare Parts A and B fee-for-service expenditures below the updated benchmark.
- The ACO is a low revenue ACO at the time of financial reconciliation for the relevant performance year.
- The ACO has at least 5,000 assigned beneficiaries at the time of financial reconciliation for the relevant performance year.

Eligible ACOs that meet the quality performance standard to share in savings at the maximum sharing rate would receive only half of the maximum shared rate (20 percent instead of 40 percent under Levels A and B, and 25 percent instead of 50 percent under Levels C, D, and E). For eligible ACOs that do not meet the quality performance standard required to share in savings at the maximum sharing rate but meet the proposed alternative quality performance standard, the sharing rate would be further adjusted according to that proposal, which would reinstate a sliding scale approach for determining shared savings using the ACO's quality performance score, including the health equity adjustment bonus points (if finalized) described earlier. **CMS seeks comment on this proposal to expand the criteria ACOs can meet to qualify for shared savings under the BASIC track.**

g. Ongoing Consideration of Concerns about the Impact of the Public Health Emergency (PHE) for COVID-19 on ACOs' Expenditures

Due to the COVID-19 PHE, CMS previously made the following changes affecting the Shared Savings Program (including some required by law):

[16] High revenue ACOs in the BASIC track, ACOs below 5,000 assigned beneficiaries at the time of financial reconciliation, and ACOs in the ENHANCED track would not be eligible for this option. CMS acknowledges that this proposal differs from the eligibility criteria for AIPs, which are limited to ACOs that are new to the Shared Savings Program, because the AIP policy is intent on lowering barriers to entry.

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- Offered relief to all ACOs that may have been unable to completely and accurately report quality data for 2019 due to the PHE;
- Allowed ACOs whose current agreement periods expired on December 31, 2020, the option to extend their existing agreement period by 1 year;
- Allowed ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for PY 2021;
- Adjusted certain program calculations to remove payment amounts for episodes of care for treatment of COVID-19, specifically the following:
    - Calculation of 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;
    - Calculation of FFS expenditures for assignable beneficiaries for determining county-level FFS expenditures and national Medicare FFS expenditures;
    - Calculation of Medicare Parts A and B FFS revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track;
    - Calculation of 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 of identifying whether an ACO is a high revenue ACO or low revenue ACO and for determining an ACO's eligibility for participation options; and
    - Calculation or recalculation of the amount of the ACO's repayment mechanism.
- Expanded the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication;
- Suspended Medicare sequestration adjustments;[17]
- Held no ACOs liable for shared losses for performance years 2020 and 2021, as those losses were fully mitigated by the adjustment for "extreme and uncontrollable circumstances," for which the PHE for COVID-19 qualified; and
- Suspended the 2021 application cycle for new applicants.

As a result of forgoing the 2021 application cycle for new applications, agreement periods starting in 2022 are the first agreement periods for which 2020 and 2021 would serve as ACO benchmark years. CMS reviews feedback and potential alternatives for addressing the effects of the PHE on ACO benchmarking calculations. OACT analyses found that sharp declines in spending in 2020 tended to rebound in 2021 such that historical benchmarks averaged across a base period including both 2020 and 2021 would appear to represent a reasonable basis from which to update ACO spending targets going forward.

[17] The sequestration adjustment was phased back in, from April 1 to June 30, 2022, at 1 percent. Starting July 1, 2022, sequestration increased to 2 percent. Fully in effect (2 percent), CMS is required to make a 2 percent reduction to shared savings payments that is applied before applying an ACO's shared savings limit. As a result of the suspension of sequestration in 2020 and 2021, shared savings payments made in 2020 and 2021 were roughly 2 percent higher than they would have been otherwise for ACOs that did not earn shared savings in excess of their shared savings limit.

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CMS believes that the current blended national-regional trend and update factors would be sufficient to address and mitigate the impact of the start of the PHE for COVID-19 on benchmark year expenditures. CMS believes the proposal to utilize a three-way blend of the ACPT/national-regional growth rates to update benchmarks (described earlier in this summary) would further mitigate any potential adverse effects of the PHE on historical benchmarks while also protecting against unanticipated variation in performance year expenditures and utilization resulting from a future PHE. **CMS seeks comment on this analysis regarding the impact of the PHE for COVID-19 on Shared Savings Program ACOs' expenditures.**

h. Proposed Supplemental Payment for Indian Health Service and Tribal Hospitals and Hospitals located in Puerto Rico

CMS currently excludes Indirect Medical Education (IME), Disproportionate Share Hospital (DSH) and uncompensated care payments from ACOs' assigned and assignable beneficiary expenditure calculations because CMS does not want to incentivize ACOs to avoid the types of providers that receive these payments, and for other reasons described in earlier rulemaking. In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28396 through 28398), CMS is proposing to establish a new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico, beginning in FY 2023.

In this proposed rule, CMS would exclude these new supplemental payments (if finalized) from the determination of Medicare Parts A and B expenditures for purposes of calculations under the Shared Savings Program, consistent with the treatment of IME, DSH and uncompensated care payments.[18] However, when calculating ACO participant revenue,[19] CMS proposes to include these new supplemental payments (if finalized), also consistent with the treatment of IME, DSH and uncompensated care payments. **CMS seeks comment on this proposed change to account for the new supplemental payments for IHS/Tribal hospitals and hospitals located in Puerto Rico (if finalized) within the Shared Savings Program.**

i. Organization and Structure of the Regulations text within 42 CFR Part Subpart G; Technical and Conforming Changes

CMS notes that to date it has tended to include the entirety of the benchmarking methodology applicable to ACOs, based on their agreement period start date, within a single section of the regulations (42 CFR part 425 subpart G). It notes, however, there are currently a limited number of unused sections within that range and no remaining sections in sequential order following the existing benchmarking sections. This section discusses how it plans to restructure the regulations to incorporate the proposed modifications to the benchmarking methodology. The technical details of its proposed technical and conforming changes can be found in this section.

[18] If included, they would have affected the determination of benchmark and performance year expenditures.
[19] ACO participant revenue is used for determining whether an ACO is a low-revenue or high-revenue ACO, and for determining the revenue-based loss sharing limits under two-sided models of the BASIC track's glide path.

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6. Reducing Administrative Burden and Other Policy Refinements

CMS proposes 2 burden reduction proposals related to ACO marketing materials and beneficiary notification requirements. Also proposed are refinements to the SNF 3-day rule waiver process and data sharing regulations. All proposals would begin with PY 2023.

a. Requirements for ACO Marketing Materials (§425.310)

CMS proposes to eliminate the requirement for an ACO to submit marketing materials to CMS for review and approval prior to their dissemination and reorganizes the regulation text of the section on Marketing Requirements. CMS notes that only 1 of 241 marketing items undergoing advance review in 2021 was denied. ACOs will remain subject to sanctions (including termination) if they fail to comply with the requirements of the reorganized section.

The reorganized section will continue to require that marketing materials and activities must (1) utilize CMS template language if available, (2) be non-discriminatory, (3) comply with regulations regarding beneficiary incentives at §425.304, and not be materially inaccurate or misleading. CMS also retains its authority to request the submission by an ACO at any time of its marketing materials and will continue to issue written notices to ACOs if materials are disapproved. ACOs and their participants and providers/suppliers will continue to be obligated to discontinue use of disapproved materials.

b. Beneficiary Notification Requirements (§425.312)

CMS proposes to reduce the frequency with which beneficiary information notices are provided to beneficiaries from annually to a minimum of once per agreement period. The notice must be in the form and manner specified by CMS. At the beneficiary's next primary care service visit or no later than 180 days after the notice has been provided, the beneficiary must be given a meaningful opportunity to engage with an ACO representative and to ask questions. The follow-up communication opportunity may be verbal or written but must be tracked and documented by the ACO. Documentation must be made available to CMS upon request. The communication interaction does not create a billable service.

CMS also proposes to clarify requirements for posting of beneficiary notification signage in facilities where ACO participants furnish services. The signage informs beneficiaries of the availability of standardized written notices about (1) the ACO and its participants, (2) the beneficiary's option to deny sharing of claims data that are identifiable at the beneficiary-level, and (3) the option to designate an ACO provider through the voluntary assignment process.

CMS clarifies that signage must be posted in all ACO facilities whether or not primary care services are furnished therein. CMS further clarifies that only primary care facilities must furnish the standardized written notice upon beneficiary request. Clarifications will be codified in a newly proposed and redesignated section at §425.312(a)(2)(i).

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CMS believes the changes are responsive to ACOs' concerns that current notification requirements are redundant and confusing to beneficiaries. CMS also notes its ongoing efforts to improve the clarity and relevance of its template notification materials.

c. SNF 3-day Rule Waiver Process (§425.612)

CMS proposes to streamline the process by which an ACO that bears two-sided risk can request a waiver of the SNF 3-day rule, such that an assigned beneficiary can be discharged to and receive inpatient SNF care without a prior 3-day inpatient hospital stay. The beneficiary must be admitted to a SNF Affiliate of the ACO and the SNF must be rated at 3 stars or higher in the CMS 5-star quality rating system.

To reduce the waiver process burden, CMS proposes to drop the requirement that the ACO submit 3 narratives with its application—communication plan, care management plan, and beneficiary evaluation and admission plan. The ACO would be required to provide to CMS upon request narrative materials about its capacity to manage patients under the waiver if granted. CMS has found that the narrative materials have not added value beyond the information contained in other application documents for use in assessing an ACO's capacity to appropriately and safely implement the waiver. Regulation text changes would be made at §425.612(a)(1)(i)(A).

d. Data Sharing Regulations (§425.702)

CMS proposes to update the regulations that govern data sharing by CMS with ACOs by allowing ACOs operating as organized health care arrangements (OHCA) to request aggregate reports and beneficiary-identifiable claims data reports from CMS.

An OHCA is defined under 45 CFR §160.103 (HIPAA regulations) to include an organized system of health care in which more than one covered entity participates and in which the participating covered entities hold themselves out to the public as participating in a joint arrangement and participate in specified joint activities such as quality assessment and improvement activities and payment activities. CMS notes that joint guidance issued by the Office for Civil Rights and the Office of the National Coordinator for Health Information Technology recognizes that ACOs may operate as OHCAs.

CMS states that operating as an OHCA allows an ACO to (1) share protected health information (PHI) among the covered entities in the OHCA without getting authorization from individuals for purposes of the OHCA's health care operations and (2) share PHI for the health care activities of the OHCA without entering into business associate agreements with each other. CMS also believes that the OHCA structure responds to ACO concerns related to gathering and reporting data on ACO patients who are not Medicare beneficiaries once the required transition to all-payer quality measures (eCQMs/MIPS CQMs) is fully implemented for PY 2025.

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7. Seeking Comment on Incorporating an Administrative Benchmarking Approach into the Shared Savings Program

a. Background on Longer Term Approach to Benchmarking under the Shared Savings Program

In this section, CMS seeks comment on an alternative approach to calculating ACO historical benchmarks that would use administratively set benchmarks that are decoupled from ongoing observed FFS spending. It states that benchmarks are a core policy instrument for providing sufficient incentives for ACOs to enter and remain in the Shared Savings Program, with significant implications on impacts to the Medicare Trust Funds. CMS has observed that the benchmarking methodology for the Shared Savings Program and Innovation Center models may include ratchet effects that reduce benchmarks for successful ACOs and jeopardize their continued participation over multiple agreement periods, resulting in selective participation (including limited participation by inefficient ACOs).

CMS states that there are two ways in which the use of factors based on realized FFS spending (which reflects any ACO spending reductions) can lead to lower benchmarks, which it refers to as "ratchet" effects: (1) downward pressure on an individual ACO's benchmark resulting from the impact of its achieved spending reductions on its historical benchmark expenditures, regional adjustment, and update factor; and (2) downward pressure on benchmarks due to program-wide spending reductions across all ACOs. The first type of ratchet effect occurs at the individual ACO level, when an ACO's own savings reduce its benchmark, which can occur when CMS resets the historical benchmark at the start of the ACO's second or subsequent agreement period. The second type of ratchet effect occurs at the program level, where overall program success can apply downward pressure on ACOs' benchmarks through the method for updating benchmarks each performance year for changes in expenditures between Base Year 3 (BY3) and the performance year. MedPAC and researchers are also examining the Shared Savings Program benchmarking methodology and have noted many of the above concerns that eliminating ratcheting effects is essential for the long-term sustainability of the Shared Savings Program.

The RFI seeks to gather information regarding a potential alternative approach to calculating ACO historical benchmarks that would use administratively set benchmarks that are decoupled from ongoing observed FFS spending.

b. Administratively Established Benchmarks as a Potential Solution to Address Benchmarking Concerns

In this section, CMS describes and seeks comment on a direction for future benchmarking that is designed to create a sustainable pathway for long-term program savings for both ACOs and CMS and to address interested parties' concerns around ratcheting. Within this section, CMS provides an overview of and discusses details of key components of this approach.

This approach involves separating benchmarking update factors from realized FFS expenditure growth through the implementation of a prospective, administratively set annual growth rate to update benchmarks. Under this approach, benchmarks would be allowed to rise above realized

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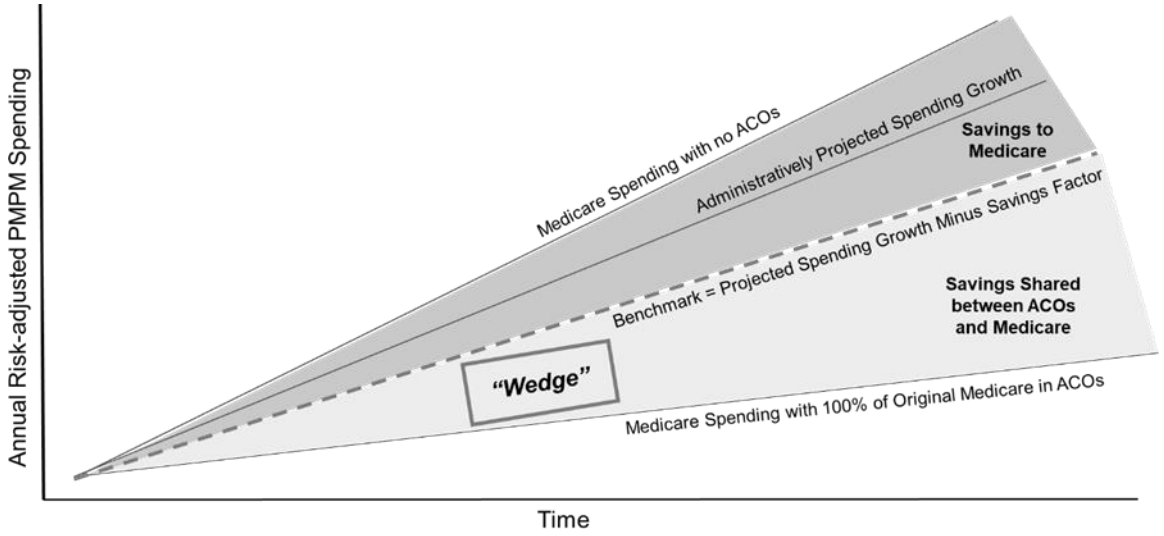
FFS expenditure growth as ACOs generate savings, allowing ACOs to retain more of their savings and thus strengthening incentives to participate and achieve savings. Over time, use of this administratively set growth rate would allow for a wedge to accrue between average benchmarks and realized spending reductions, offering greater and more sustainable savings opportunities over the long-term for both Medicare and ACOs. Importantly, average benchmark growth would only exceed realized FFS spending growth to the extent that ACOs reduce spending, such that benchmarks remain at or below FFS spending levels projected in the absence of ACO participation. A graphic depiction of administratively-established benchmarking is provided in Figure 3 in the proposed rule (reproduced below).

Figure 3: Illustrative Example of Administratively-Established Benchmarking Approach



CMS believes that an administrative set benchmarking approach also offers a path for converging benchmarks gradually towards a common risk-adjusted rate in each region, which it anticipates would mitigate selective participation and improve the savings potential of the program. As long as ACOs are generating savings collectively, CMS believes that this approach would allow all ACOs a chance to earn shared savings while reducing overall spending relative to projections and protecting the Trust Funds. In addition, benchmarks that exceed FFS spending would give ACOs flexibility to meet beneficiary needs through alternative modes of care such as virtual care or care management programs that have not traditionally been reimbursed under FFS.

CMS seeks comment on these concepts and on the design of an administratively established benchmarking methodology. It provides more details on its approach in subsequent sections of the proposed rule. It also welcomes comments on the stages for implementing such an approach within the Shared Savings Program, particularly on an initial convergence phase and a post-convergence phase, and any other considerations related to this approach that it has not addressed in this proposed rule. It also seeks comment on any additional modifications to the design of the Shared Savings Program that should be considered in conjunction with administratively set benchmarks.

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CMS states that establishing administratively established benchmarks would require it to use its authority under section 1899(i)(3) of the Act. This requires that the alternative payment methodology will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures. **CMS seeks comment on the extent to which the use of administratively set benchmarks might have the potential to improve the quality and efficiency of care furnished to Medicare beneficiaries and any anticipated impact on Medicare expenditures.**

c. Establishing an Administrative Benchmark Update Factor

(1) Overview

Under the administratively-established benchmarking concept, CMS would continue to utilize an ACO's historical FFS expenditures to establish the ACO's historical benchmark. It would modify the existing methodology to fully remove negative regional adjustments to the benchmark, but otherwise retain much of the existing methodology. CMS describes its approach more fully in the subsequent sections.

(2) Use of Accountable Care Prospective Trend in the Benchmark Update

CMS is considering an approach that would transition the proposed three-way blend between the prospective Accountable Care Prospective Trend (ACPT) and retrospectively determined regional and national growth rates (as described in section III.G.5.c. of this proposed rule) to an entirely prospectively set trend. For this trend, OACT would calculate an ACPT, based on a modification of the existing USPCC growth projections used annually for establishing Medicare Advantage rates. It believes that an ACPT with some additional modifications could serve as the core component of the administratively set benchmark update under the longer-term approach.

CMS is considering an approach under which it would establish an ACPT every 5 years which would apply during that 5-year window. It is considering maintaining separate projections within the ACPT for price growth, volume/intensity growth, and demographic factors (with potential exceptions for certain service types such as Part B drugs, which are not currently projected using disaggregated growth assumptions). CMS states that it would also need to establish a process for considering additional factors when recalculating the ACPT prospective update factor every 5 years.

CMS seeks comment on these considerations for calculating an ACPT to be used as an administratively set benchmark update factor. It seeks comment on the 5-year intervals for establishing an ACPT, and alternative approaches that would tie the ACPT to an ACO's agreement period. It also seeks comment on approaches to accounting for price growth and demographic factors versus volume/intensity and considerations for guardrails to protect against projection error. Finally, it seeks comment on approaches to updating the ACPT that would ensure it does not overly reflect ACOs' collective impact on spending.

(3) Discount Factor

CMS believes that under its approach there would need to be a period of gradual convergence in spending between efficient and inefficient ACOs. Its approach would be to subtract a modest

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annual discount factor from the fixed 5-year ACPT growth trend based on the relative efficiency of the ACO. For example, if the projected ACPT trend was 5.1 percent annual growth, an ACO with a 0.2 percent discount factor would have a benchmark update factor based on a 4.9 percent annual growth rate (5.1 percent minus 0.2 percent).

To determine what discount would be applied to an ACO's update factor, it would calculate a measure of the ACO's regional efficiency. CMS would compare the ACO's historical spending (the weighted-average spending for the ACO in benchmark year 3) to a regional benchmark (the weighted-average regional FFS expenditures for benchmark year 3). If an ACO's historical spending was greater than its regional benchmark, CMS would apply a discount to the amount of the benchmark update, scaled such that a larger discount is applied for ACOs with increasingly higher spending (less efficient) compared to their regional benchmark. No discount would be applied to the update amount for ACOs with spending 2 percent or more below their regional benchmark. The discount would vary according to the regional efficiency of each participating ACO but, importantly, would not grow if an ACO successfully lowers spending. The calculation would also take into account changes in composition of ACO participant TINs during an agreement period.

CMS seeks comment on this approach for calculating and applying a discount factor in determining the amount of an ACO's benchmark update. It seeks comment on the intervals of the discount described, and alternative approaches such as use of a sliding scale in determining the discount amount. It also seeks comment on approaches to ensuring the discount is reflective of the ACO's regional efficiency, including the approach of recalculating the discount factor to reflect changes in an ACO's regional efficiency as a result of changes in the ACO's composition during its agreement period.

(4) Removal of Negative Regional Adjustments to the Benchmark

In the administratively-established benchmarking concept, CMS would no longer apply negative regional adjustments to the benchmark, although positive regional adjustments would remain. Under this approach, ACOs with higher-than-average historical spending would begin with a benchmark calculated solely using their historical experience. It is also considering approaches for addressing a potential concern that efficient ACOs would be disincentivized from adding less efficient providers and suppliers as ACO participants because it would reduce their regional adjustment. One approach would be to scale an ACO's initial, larger positive regional adjustment based on the overlap in beneficiaries that would have been aligned to the ACO using the ACO's initial ACO participant list and its updated ACO participant list.

CMS seeks comment on this approach, and considerations related to removing the negative regional adjustment in establishing the ACO's historical benchmark under an administratively- established benchmark approach. It also seeks comment on considerations for limiting disincentives for efficient ACOs to add less efficient providers and suppliers.

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(5) Detailed Administratively-Established Benchmark Update Calculation

CMS seeks comment on the step-by-step example of the administratively-established benchmark:

Step 1: Calculate the historical benchmark according to the existing Shared Savings Program benchmarking methodology, without applying negative regional adjustments.

Step 2: Risk-adjust the historical benchmark to account for changes in severity and case mix between BY3 and the performance year for each enrollment type.

Step 3: Apply the update factor to the risk-adjusted historical benchmark for each enrollment type, calculated as follows:

++ Start with the overall OACT-projected Shared Savings Program ACPT 5-year projected trend applicable for the ACO based on the start of its agreement period and the performance year for each enrollment type. The update rate over an agreement period may include ACPT projected trends from more than one 5-year period if the ACO's agreement period does not align with the 5-year cycle for ACPT calculation.

++ Apply the average projected trend based on the number of years between BY3 and the performance year.

++ Apply any retrospective adjustments to the trend based on divergence between the price and demographic components of the ACPT projected trend and observed price trends and demographic changes. This retrospective adjustment would be calculated annually after the end of each performance year only for the price and demographic components (no such adjustment would be made for the volume-intensity component).

++ Subtract the relevant discount factor (as per the examples in Table 70, based on the regional efficiency of the ACO in BY3) from the adjusted trend for each year between BY3 and the performance year to determine the ACO's trend percentage.

++ Multiply the ACO's trend percentage by the average national ACPT value for assignment eligible beneficiaries (adjusted to reflect the ACO's relative risk in each eligibility category) to determine the flat dollar update amount.

++ Apply any guardrails as described in section III.G.7.c.(2) of this proposed rule.

++ Add the flat dollar update amount to the ACO's risk-adjusted historical benchmark for the applicable enrollment type.

Step 4: Calculate a single per capita benchmark amount by taking a weighted average across each enrollment type.

d. Convergence to Regional Benchmarks; Post-Convergence Phase

CMS believes that ultimately, this administratively-established benchmark approach would be partially intended to drive ACOs towards regional spending convergence. It believes that this

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post-convergence phase would completely eliminate ratcheting effects by removing rebasing and would also decouple benchmarks from an ACO's historical spending, thereby creating a sustainable benchmarking approach that would support high ACO participation levels and reward ACOs for increased efficiency. The convergence phase would be intended to converge benchmarks toward some level above realized spending, but below predicted spending absent ACOs, assuming ACOs generate savings. It anticipates that this convergence phase will last between 5-10 years, depending on participation rates and the pace of spending convergence within regions. If the convergence phase takes longer than 5 years, CMS states that it would need to address the potential rebasing effects for ACOs renewing for subsequent agreement periods under the new benchmarking approach.

CMS seeks comment on—

- Considerations for the design of a regionally consistent benchmarking approach, including how to set fair and accurate risk-standardized benchmarks, the process for annual updates to regional rates, and how to distinguish between enrollment types.
- Considerations for the required conditions and timing for reaching this post-convergence phase with the use of regionally consistent benchmarks, as well as incentives to promote ACO spending convergence within a region.
- Approaches to addressing rebasing effects for renewing and re-entering ACOs in subsequent agreement periods during the convergence phase.
- Considerations for converging to nationally consistent spending versus regionally consistent spending.

e. Request for Comment on Addressing Health Equity Through Benchmarking

CMS states that benchmarks based on historically observed spending may be inequitable to the extent that historical patterns reflect existing inequities in both access to care and the provision of care. It is interested in considering how direct modification of benchmarks to account for existing inequities in care can be used to advance health equity. Direct increases to benchmarks for historically underserved populations would grant additional financial resources to health care providers accountable for the care of these populations, and may work to offset historical patterns of underspending that influence benchmark calculation.

CMS discusses the ACO REACH health equity benchmark adjustment as an example to address inequity in benchmarks calculated primarily using historical expenditures, where historical underspending for underserved beneficiaries informs benchmarks. It believes that these and other approaches could be employed to preserve (if not expand) existing payment differentials that set payment higher for certain providers. Equity-motivated benchmark adjustments could be implemented, for example, to support additional funding for safety net providers (for example, CAHs, RHCs, and FQHCs). In other cases, add-on payments, such as DSH and IME, might continue to be carved out of ACO benchmarks and performance year expenditures, as they are now. **CMS seeks comment on other policy adjustments that should be considered for benchmark setting in the post-convergence phase. This includes:**

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- Approaches, generally, to addressing health inequities via the benchmark methodology for the Shared Savings Program, and specifically to incentivize ACOs to serve historically underserved communities.
- Considerations for what data would need to be collected on Medicare beneficiaries and their communities (for example, need for and access to health care providers, transportation, and social services) and what factors should be considered to identify underserved communities and adjust ACO benchmarks.
- Considerations for including a health equity benchmark adjustment in the Shared Savings Program in the near term comparable to the equity adjustment being tested within the ACO REACH Model.
- Considerations for addressing health inequities in the context of the benchmarking concept outlined in this section of this proposed rule.
- Considerations for monitoring and program integrity tools that would track the use of any health equity benchmark adjustments for the intended purposes.
- Considerations for whether benchmark adjustments for ACOs that include CAHs, RHCs, FQHCs, and REHs as ACO participants would improve care for rural and underserved populations and increase participation by these providers and suppliers in the Medicare Shared Savings Program.

8. Impact on Medicare Shared Savings Program

CMS notes that its proposed policies are designed to reverse recent trends where participation has plateaued in the Shared Savings Program, higher spending populations are increasingly underrepresented in the program, and access to ACOs appears inequitable. It believes that the overall increase in shared savings payments to ACOs transitioning to the ENHANCED track appears to be driven largely by favorable regional benchmark adjustments and the track's higher sharing rate. Without modifications, CMS believes that the program is at high risk of increasing overall Medicare spending over the coming decade. Its new proposals are designed to increase program participation for new ACOs through advance investment payments to promote health equity and provide ACO's greater choice in the pace of progression to performance-based risk. It also believes that reducing the cap on negative regional adjustments to high spending ACO benchmarks and offering eligible ACOs a shared savings-only BASIC track participation option for a full 5-year agreement period is expected to significantly re-engage participation for ACOs serving high-cost beneficiaries. This is particularly true for low revenue physician led ACOs for whom a 40 percent sharing rate is a strong incentive for efficiency even absent downside risk.

The proposed rule changes are estimated to reduce overall program spending by $14.8 billion over 12 years relative to the $4.2 billion cost anticipated for the trajectory of the program at baseline, or $10.6 billion in absolute terms relative to a baseline without a Shared Savings Program in FFS Medicare (See Table 142, reproduced below). The impact estimate ranges from a reduction of $8.2 billion to a reduction of $21.4 billion at the 10th an 90th percentiles. CMS anticipates that about 80 percent of advance investment payments are anticipated to be recovered from shared savings payments by the middle of the second agreement period after an initial

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investment of $210 million. It also estimates that approximately $60 million in net savings for 2023 is projected for retaining existing higher-spending ACOs that would have otherwise dropped out if not offered the ability to remain in one-sided risk for the remainder of their current agreement period.

Table 142: Proposed Rule Projected Impact Relative to Current SSP Baseline (Financial Impacts in $Millions)

Program Year	ACO Participation	ACO Benchmark	Claims	Net ACO Sharing	Advance Investment Cash Flow*	Comb. Fed Impact
2023	34	10,940	-80	20	N/A	-60
2024	128	40,040	-490	70	210-70	-420
2025	140	43,490	-760	-200	-40	-960
2026	137	44,110	-950	-120	-20	-1,070
2027	138	45,800	-1,170	-70	-10	-1,240
2028	143	49,060	-1,370	-40	-10	-1,410
2029	155	54,930	-1,700	-10	-10	-1,710
2030	146	53,700	-1,990	310	-10	-1,680
2031	144	55,210	-2,110	310	0	-1,800
2032	144	57,130	-2,100	220	0	-1,880
2033	138	56,820	-2,120	250	0	-1,870
2034			-670	-90	0	-760
12Y Total			**-15,510**	**650**	**40**	**-14,810**
Low (10th Ptile)				-3,710		-21,410
High (90th Ptile)				820		-8,200
*Total advance investment payments in 2024 shown with first year repayment amount in same row for 2024						

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TAB 6

Physician Fee Schedule Proposed Rule for 2023
Summary Part II

Medicare and Medicaid Program: 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

[CMS-1770-P]

On July 7, 2022, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule relating to the Medicare physician fee schedule (PFS) for CY 2023[1] and other revisions to Medicare Part B policies. The proposed rule is scheduled to be published in the July 29, 2022 issue of the *Federal Register*. If finalized, policies in the proposed rule generally would take effect on January 1, 2023. **The 60-day comment period ends at close of business on September 6, 2022.**

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

Part II includes proposals related to the Medicare Shared Savings Program. These are designed to strengthen financial incentives for long-term participation by modifying the benchmarking methodology, expanding opportunities for certain low revenue ACOs and those serving high risk and dual eligible populations. It also aims to make operational improvements to reduce administrative burden and makes numerous revisions to the quality reporting and the quality performance requirements.

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[1] Henceforth in this document, a year is a calendar year unless otherwise indicated.

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1. Executive Summary

Under the Shared Savings Program, providers and suppliers that participate in an Accountable Care Organization (ACO) continue to receive traditional Medicare 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, 2022, over 11 million people with Medicare receive care from one of the 528,966 health care providers in the 483 ACOs participating in the Shared Savings Program.

CMS says policies in this proposed rule are intended to reverse the following recent trends in the Shared Savings Program and to **advance equity** (CMS' emphasis):

- In recent years, growth in the number of beneficiaries assigned to ACOs has plateaued.
- Higher-spending populations are increasingly underrepresented in the program since the change to regionally adjusted benchmarks.
- Access to ACOs appears inequitable as shown by data indicating that Black (or African American), Hispanic, Asian/Pacific Islander, and American Indian/Alaska Native beneficiaries are less likely to be assigned to an ACO than their Non-Hispanic White counterparts.

CMS cites feedback from health care providers treating underserved populations—that they require upfront capital to make the necessary investments to succeed in accountable care and may also need additional time under a one-sided model before transitioning to performance-based risk (also known as a two-sided model). Thus, CMS proposes to provide advance shared savings payments to low revenue ACOs that are inexperienced with performance-based risk Medicare ACO initiatives, that are new to the Shared Savings Program, and that serve underserved populations. These advance investment payments (AIPs) would increase when more beneficiaries who are dually eligible for Medicare and Medicaid or who live in areas with high deprivation (measured by the area deprivation index (ADI)),[4] or both, are assigned to the ACO. These funds—a one-time fixed payment of $250,000 and quarterly payments for the first 2 years of an ACO's 5-year agreement period, remaining available for use over the 5-year period—would be available to address the social needs of people with Medicare, as well as health care provider staffing and infrastructure. CMS says additional proposed modifications would support organizations new to accountable care by providing greater flexibility in the progression to performance-based risk, allowing these organizations more time to redesign their care processes to be successful under risk arrangements.

[2] In this section of the summary, all references to ACOs are to ACOs participating in the Shared Savings Program.
[3] Section 1899 of the Act contains statutory provisions of the Shared Savings Program, with regulations codified at 42 CFR part 425.
[4] The preamble of the proposed rule describes the background of the ADI measure and how it is calculated. The ADI data files are publicly available for download at https://www.neighborhoodatlas.medicine.wisc.edu/.

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CMS is also proposing a health equity adjustment that would upwardly adjust ACOs' quality performance scores to continue encouraging high ACO quality performance, transition ACOs to all-payer electronic clinical quality measures (eCQMs) and Merit-based Incentive Payment System clinical quality measures (MIPS CQMs), and support those ACOs serving a high proportion of underserved beneficiaries while also encouraging all ACOs to treat underserved populations. Finally, CMS is proposing certain changes to the benchmarking methodologies to encourage participation by health care providers who care for populations that include a high percentage of beneficiaries with high clinical risk factors and beneficiaries dually eligible for Medicare and Medicaid.

In this proposed rule, CMS says it is accomplishing the following:

- Strengthening financial incentives for long term participation by reducing the impact of ACOs' performance on their benchmarks;
- Addressing the impact of ACO market penetration on regional expenditures used to adjust and update benchmarks;
- Supporting the business case for ACOs serving high risk and dually eligible populations to participate;
- Modifying the benchmarking methodology to mitigate bias in regional expenditure calculations that benefits ACOs electing prospective assignment;
- Expanding opportunities for certain low revenue ACOs participating in the BASIC track (one-sided shared savings-only model) to share in savings even if they do not meet the minimum savings rate (MSR), to allow for investments in care redesign and quality improvement activities among less capitalized ACOs;
- Eliminating the requirement for an ACO to submit marketing materials to CMS for review and approval prior to disseminating materials to beneficiaries and ACO participants (but still requiring submission of marketing materials to CMS upon request);
- Streamlining the SNF 3-day rule waiver application review process;
- Reducing the frequency with which beneficiary information notices are provided to beneficiaries (from annually to a minimum of once per agreement period, with a proposed follow-up beneficiary communication serving to promote beneficiary comprehension of the standardized written notice);
- Revising data-sharing requirements to recognize ACOs structured as organized health care arrangements (OHCAs) for data sharing purposes; and
- Making numerous revisions to the quality reporting and the quality performance requirements for performance year 2023 and subsequent performance years.

CMS anticipates that the Shared Savings Program proposals will increase participation, particularly from ACOs serving beneficiaries with greater needs and higher baseline spending. The incentive for ACOs to reduce spending over multiple agreement periods is also expected to be bolstered—for example, by reducing the weighting on the regional component of the benchmark update and by providing a prior savings adjustment at rebasing.

CMS projects a $15.5 billion decrease in spending on benefits (that is, savings from efficiency) and $650 million in higher net shared savings payments to ACOs, resulting in $14.8 billion lower overall spending compared to the program baseline.

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To make these changes, CMS cites the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. Specifically, CMS lists the following proposals as requiring use of 1899(i) authority:

- Allowing for AIPs;
- Modifying the calculation of the shared loss rate under the ENHANCED track to allow for a sliding scale based on an alternative quality performance standard;
- Incorporating a prospectively projected administrative growth factor—a variant of the United States Per Capita Cost (USPCC), referred to in this proposed rule as the Accountable Care Prospective Trend (ACPT)—into a three-way blend with national and regional growth rates to update an ACO's historical benchmark and address increasing market saturation by ACOs in a regional service area;
- Expanding the 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 MSR as required under section 1899(d)(1)(B)(i) of the Act; and
- Excluding the proposed new supplemental payment for Indian Health Service (IHS)/Tribal hospitals and Puerto Rico hospitals from the determination of Medicare Parts A and B expenditures used in certain financial calculations under the Shared Savings Program.

These provisions are summarized in greater detail below.

2. Shared Savings Program Participation Options

a. Increasing Participation in Accountable Care Models in Underserved Communities by Providing an Option for Advance Investment Payments to Certain ACOs

CMS lays out the rationale for the new AIPs by describing a need for start-up ACO investment, relying on the experience of prior models that provided such funding. CMS acknowledges that the start-up investment costs for an ACO can be substantial, particularly for a small organization or an organization caring for underserved or more medically complex patients. The CMS Innovation Center previously tested two models to assess whether such up-front payments would increase participation in the Shared Savings Program by ACOs serving rural or underserved regions—the Advance Payment (AP) ACO Model, which operated from 2012 to 2015, and the ACO Investment Model (AIM), which operated from 2015 to 2018. Both models operated by prepaying shared savings to ACOs and later recouping those amounts from earned shared savings (if any).

AP ACOs received between $1.3 million and $2.7 million in prepaid shared savings, via an up-front payment of $250,000 per ACO plus $36 per beneficiary, followed by an $8 per beneficiary per month payment for 2 years. In AIM, the prepaid shared savings amounts were distributed and recouped in the same amounts and manner as the AP ACO model for the majority of model participants. The AP Model did not significantly improve the quality or cost of care. However,

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AIM successfully encouraged ACOs to form in areas where ACOs may not have otherwise formed and where other Medicare payment and delivery innovations were less likely to be present. AIM generated an estimated net aggregate reduction in spending by Medicare of $381.5 million after accounting for Medicare's payment of AIM funds and ACOs' earned shared savings, without reducing the quality of care provided to beneficiaries. CMS acknowledged continued interest in the AIM and AP ACO models and approaches with similar up-front and ongoing payments for ACOs newly participating in the Shared Savings Program.

Consequently, CMS proposes to make advance shared savings payments—referred to as advance investment payments (AIPs)—to certain ACOs participating in the Shared Savings Program, to improve the quality and efficiency of items and services furnished to Medicare beneficiaries. Such payments would be made in accordance to standards proposed in a new 42 CFR §425.630.

CMS envisions that this new payment option would distribute AIPs to ACOs for 2 years in order to reduce the financial barriers encountered by small providers and suppliers as they join the Shared Savings Program. These payments would be recouped from shared savings the ACO earned, if any.

AIP Eligibility. CMS proposes to limit eligibility for AIP funding to new ACOs and ACOs inexperienced with performance-based risk Medicare ACO initiatives. AIP eligibility builds on AIM, but with more inclusive eligibility criteria that CMS considers necessary to scale advance payments from a model to a regular component of the Shared Savings Program and to align with the Innovation Center's stated vision for health care transformation. CMS is also broadening the eligibility criteria compared to AIM to reflect its belief that it is important to provide an incentive for providers and suppliers who serve high need beneficiaries in all areas to form ACOs, including underserved beneficiaries who reside in urban areas. Therefore, CMS does not limit the opportunity for an ACO to receive AIPs to ACOs in only rural communities or in areas with low ACO penetration.

Specifically, in proposed §425.630(b), an ACO would need to meet all of the following criteria to be eligible for AIPs:

- Not a renewing ACO or re-entering ACO;
- Has applied to participate in the Shared Savings Program under any level of the BASIC track glide path (because this participation option is indicative of an ACO's inexperience with performance-based risk, in which ACOs are typically less experienced with risk and are more likely to benefit from up-front funding or ongoing financial assistance);
- Eligible to participate in the Shared Savings Program;
- Inexperienced with performance-based risk Medicare ACO initiatives; and
- A low revenue ACO (defined in current §425.20 as having less than 35 percent of its Medicare A and B fee-for-service revenue through assigned beneficiaries based on the most recent calendar year for which 12 months of data are available).

CMS seeks comments on these proposals.

AIP Application Procedure. The initial application cycle to apply for AIPs would be for a January 1, 2024, start date. In the new §425.630(c), CMS proposes to codify the application

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process for AIPs. In order to obtain a determination regarding whether an ACO may receive AIPs, it must submit, as part of its application to participate in the Shared Savings Program, complete supplemental application information in the form and manner and by a deadline specified by CMS.

The application cycle for AIPs would be conducted as part of and in conjunction with the Shared Savings Program application process, with instructions and timelines published through the Shared Savings Program website. As previously mentioned, ACOs currently participating in the Shared Savings Program or applying to renew their participation agreement would not be eligible to apply. CMS intends to provide further information regarding the process, including the application and specific requirements such as the deadline for submitting applications, through subregulatory guidance and will also provide a feedback process to afford an opportunity for the applicant to clarify or revise its application.

AIP application contents. As proposed in the new §425.630(d), an ACO would be required to submit a spend plan as part of its application for AIPs. The spend plan must:

- Identify how the ACO will spend the AIPs during the agreement period to build care coordination capabilities (including coordination with community-based organizations, as appropriate),
- Address specific health disparities,
- Meet other criteria under §425.630,
- Identify the categories of goods and services that will be purchased with AIPs, the dollar amounts to be spent on the various categories, and such other information as may be specified by CMS, and
- State that the ACO will establish a separate designated account for the deposit and expenditure of all AIPs.

CMS says it does not intend for the proposed spend plan to create a benchmark requirement against which it would hold the ACO accountable, but rather it is intended to aid CMS in tracking ACO progress toward implementing their spend plan and any challenges or changes in strategy that occur following their receipt of AIPs.

Use and Management of AIPs. Although current regulations do not require an ACO to spend its shared savings in any particular way, CMS proposes to specify how an ACO may use AIPs, citing three reasons:

- The purpose of AIPs,
- The fact that AIPs are made before any shared savings are actually earned by an ACO, and
- CMS' proposed limitations on the recovery of AIPs in the absence of earned shared savings.

Thus, an ACO must use AIPs to improve the quality and efficiency of items and services furnished to beneficiaries by investing in the following categories:

- Increased staffing,
- Health care infrastructure, and

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- The provision of accountable care for underserved beneficiaries, which may include addressing social determinants of health (SDOH).

CMS offers numerous examples of permitted uses within these three categories, while emphasizing that AIP amounts are advance shared savings and are not payment or reimbursement for items or services under the three specified categories. **CMS solicits comment on whether there are additional categories of expenses that should be permitted in light of the purposes of AIPs.**

In the preamble, CMS also provides examples of prohibited uses of AIPs, including management company or parent company profit, performance bonuses, other provider salary augmentation, provision of medical services covered by Medicare, or items or activities unrelated to ACO operations that improve the quality and efficiency of items and services furnished to beneficiaries. However, performance bonuses could be tied to successful implementation of SDOH screenings or care management guidelines, or ACOs could pay a higher salary as necessary to retain a clinician who treats underserved beneficiaries. The proposed regulation specifically prohibits AIPs from being used for any expense other than an allowable use or to repay shared losses of ACOs in Level E of the BASIC track. **CMS solicits comment on these examples of prohibited uses and whether there are additional categories of expenses that should be prohibited in light of the purposes of AIPs.**

To allow CMS to monitor whether the funds are used only for allowable uses and to ensure that AIPs do not pay for any prohibited uses, CMS proposes to require ACOs to segregate AIPs from all other revenues by establishing and maintaining a separate account into which the ACO must immediately deposit all AIPs and from which all disbursements of such funds are made only for allowable uses. Although CMS would deposit AIPs into the same account used for the deposit of shared savings payments, upon receipt of AIPs, the ACO must immediately deposit the funds into the separate AIP account.

AIP Methodology. During the first 2 performance years of the ACO's participation agreement, AIPs would include a one-time fixed payment of $250,000 and 8 quarterly payments based on the number of assigned beneficiaries (capped at 10,000 beneficiaries for AIP payment-calculation purposes). CMS believes that initial ACO start-up costs do not vary significantly by the size of an ACO or by the underlying level of risk of an assigned beneficiary population. However, **CMS seeks comment on the proposal to provide eligible ACOs with a one-time payment of $250,000, as well as alternatives such as allowing the one-time payment to vary based on the number of assigned beneficiaries, the risk factors of the ACO's assigned beneficiary population, or both.**

As with the one-time payment, the structure of the quarterly payments is informed by CMS' experience in AIM, where ACO participants had variable costs for clinical care management activities (such as clinical staff) supported by the per beneficiary per month payments. CMS considered monthly and additional annual payments. However, monthly payments would result in additional operation burden for CMS that is not feasible and offers little additional benefit to ACOs relative to quarterly payments, according to CMS. On the other hand, CMS believes the

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benefit to ACOs of consistent payments on a quarterly basis—compared to additional annual amounts—outweighs the administrative costs of calculating quarterly payments. **CMS seeks comment on the proposed schedule of the AIPs to ACOs.**

The ACO's upcoming quarterly payment amount would be determined prior to the start of each quarter based on the latest available assignment list for the performance year. (An alternative under consideration by CMS is based on the beneficiaries assigned to the ACO at the beginning of a performance year, which could remain fixed for the duration of that performance year. This would provide certainty regarding the amount of payments over the course of the year, but carries the risk that CMS would underpay or overpay relative to the quarterly determination. **CMS seeks comment on this alternative proposal for the quarterly payment determination.**)

The 8 quarterly AIPs would be based on the number of assigned beneficiaries (capped at 10,000), adjusted by a risk factors-based score for each beneficiary, taking into account dual-eligibility status and the ADI national percentile ranking of the census block group of the beneficiary's primary address. Specifically, CMS would complete the following steps to calculate the ACO's quarterly AIP amount:

- Step 1: Determine the ACO's assigned beneficiary population.
- Step 2: Assign each beneficiary a risk factors-based score, as follows:
    - 100 (producing maximum payment amount) if the beneficiary is dually eligible for Medicare and Medicaid—which corresponds to a quarterly payment of $45.
    - If the beneficiary is not dually eligible, assign a risk factors-based score equal to the ADI national percentile rank of the census block group corresponding with the beneficiary's primary mailing address.
    - 50 if the beneficiary is not dually eligible and cannot be matched with an ADI national percentile rank due to insufficient data—which corresponds to a quarterly payment of $28.
- Step 3: Determine the payment amount for each beneficiary, based on the risk factors-based score, shown below from Table 42 and proposed §425.630(f)(2)(iii).

Risk Factors-Based Score	**1-24**	**25-34**	**35-44**	**45-54**	**55-64**	**65-74**	**75-84**	**85-100**
Per beneficiary payment amount	$0	$20	$24	$28	$32	$36	$40	$45

- Step 4: Calculate the ACO's total quarterly payment amount. If the ACO has more than 10,000 assigned beneficiaries, CMS would calculate the quarterly payment amount based on the 10,000 assigned beneficiaries with the highest risk factors-based scores.

CMS offered various alternatives for the calculation of the quarterly AIPs, for which it seeks comments.

AIP Compliance and Monitoring. CMS proposes to monitor the spending of AIPs to provide CMS with a clear indication of how ACOs intend to spend AIPs, provide adequate protection to the Medicare Trust Funds, and to prevent funds from being misdirected or appropriated for

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activities that do not constitute a permitted use of the funds. CMS would compare the anticipated spending in the spend plan to the actual spending reported on the ACO's public reporting webpage, including any expenditures not identified in the spend plan. The reported annual spending must include any expenditures of AIPs on items not identified in the spend plan. ACOs would be required to annually report their actual expenditures via an updated spend plan on their public reporting webpage.

If CMS determines that an ACO had disbursed AIPs for a prohibited use, CMS could take compliance action in existing §§425.216 and 425.218 and could terminate the ACO's receipt of AIPs. Any AIPs that are unspent at the end of the ACO's agreement period must be repaid to CMS.

CMS is concerned about the possibility that an ACO may be eligible to receive AIPs and then quickly thereafter seek to add ACO participants experienced with performance-based risk, thereby avoiding the inexperience and low-revenue eligibility requirements. Therefore, CMS proposes to monitor ACOs that receive AIPs for changes in the risk experience of ACO participants that would cause an ACO to be considered experienced with performance-based risk or a high revenue ACO and therefore ineligible for AIPs. As proposed, the ACO would be obligated to repay spent and unspent AIPs if CMS takes pre-termination action under §425.216 and the ACO continues to be experienced with performance-based risk Medicare ACO initiatives or a high revenue ACO after a deadline specified by CMS pursuant to such compliance action (for example, the next deadline for updating the ACO participant list). To retain its AIP, an ACO that CMS determines to be experienced with performance-based risk or a high revenue ACO would be required to remedy the issue by the deadline specified by CMS. For example, if the ACO participants' total Medicare Parts A and B FFS revenue has increased in relation to total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, the ACO could remove an ACO participant from its ACO participant list so that the ACO could meet the definition of a low revenue ACO.

Although CMS' existing pre-termination actions for ACOs do not include the cessation of payments to an ACO, CMS proposes at §425.630(h) that it may immediately terminate an ACO's receipt of AIPs if the ACO does any of the following:

- Ceases to meet the eligibility requirements,
- Fails to comply with other AIP requirements, or
- Meets any of the grounds for termination set forth generally for ACOs at §425.218(b).

Recoupment. In AIM, CMS recouped prepaid shared savings from any shared savings earned by an ACO in its current agreement period, and if necessary, future agreement periods. If the ACO did not achieve shared savings, then the prepaid shared savings were not recouped. Additionally, the balance of funding was not recouped if the ACO completed the agreement period and decided not to reenroll in a second agreement period. However, if the ACO terminated prior to the end of its 3-year agreement period, the remaining balance was required to be repaid in full. During AIM, CMS observed that offering new small ACOs prepaid shared savings that they were not at risk of being forced to repay if they did not achieve savings was a critical incentive for small providers and suppliers to form ACOs to join AIM. This experience

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in AIM informs CMS' proposal at §425.630(g) for recoupment of the AIPs from an ACO in the Shared Savings Program, which now has 5-year agreement periods.

Regarding recoupment of AIPs, CMS proposes the following:

- AIPs are recouped from any shared savings earned by the ACO in any performance year until CMS has recouped all AIPs.
- If there are insufficient shared savings to recoup the AIPs in a performance year, that remaining balance would be carried over to the subsequent performance year(s) in which the ACO achieves shared savings, including any performance year(s) in a subsequent agreement period.
- CMS will not recover an amount of AIPs greater than the shared savings earned by an ACO in that performance year. Thus, if an ACO does not earn shared savings, none of the AIPs would be recouped from the ACO.
- If an ACO terminates its participation agreement during the agreement period in which it received an AIP, the ACO must repay all AIPs it received.
- The proposed regulation also contains details in the event of bankruptcy.

CMS seeks comment on all aspects of the proposals for recoupment of the AIPs made to ACOs.

b. Smoothing the Transition to Performance-Based Risk in ACOs

Background. CMS notes that the Shared Savings Program, since its inception in 2012, has included both one-sided financial models (also known as shared savings only, or upside only) and two-sided financial models (shared savings and shared losses, or upside and downside risk) for ACOs to select based on the arrangement that makes the most sense for their organization. Over the years, CMS has modified available financial models (participation options) providing "on-ramps" to attract both those that are new to value-based purchasing, as well as more experienced entities that are ready to accept two-sided risk. CMS has modified these participation options to adjust the maximum level of risk that must be assumed under two-sided models and to smooth the transition to two-sided models. In the preamble, CMS walks through the history of these modifications in the Shared Savings Program.

Most recently (December 2018 final rule at 83 FR 67822), CMS redesigned the participation options to transition more rapidly to two-sided models under two tracks—a BASIC track and an ENHANCED track. Both tracks are designed for 5-year agreement periods. The BASIC track includes a glide path with 5 Levels (A through E) that allows eligible ACOs to begin under a one-sided model for 2 years (each year of which is identified as a separate level (Levels A and B)) and advance to a two-sided model that includes incrementally higher levels of risk and reward (Levels C, D, and E) for the remaining 3 years of the agreement period. CMS allowed additional flexibility for new ACOs that qualify as low revenue ACOs inexperienced with performance-based risk Medicare ACO initiatives[5] to participate for up to 3 performance years under a one-sided model (4 performance years in the case of ACOs entering an agreement period

[5] Current regulations at §425.20 define "experienced with performance-based risk Medicare ACO initiatives" and "inexperienced with performance-based risk Medicare ACO initiatives."

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beginning on July 1, 2019) of the BASIC track's glide path before transitioning to the highest level of risk and potential reward under the BASIC track (Level E) for the final 2 years of the agreement period. Based on a combination of factors, CMS determines an ACO's eligibility for participation options in the BASIC track and ENHANCED track, along with the number of agreement periods that the ACO may participate in the BASIC track.

An ACO's ability to participate in the BASIC track is limited, and all ACOs eventually must transition to participation in the ENHANCED track to continue in the program. High revenue ACOs are limited to, at most, a single agreement period under the BASIC track prior to transitioning to participation under the ENHANCED track. Low revenue ACOs are generally limited to 2 agreement periods—for a total of 10 performance years—under the BASIC track. Current regulations require that should a low revenue ACO identified as experienced with performance-based risk Medicare ACO initiatives have changes in the revenue of its ACO participants that would cause the ACO to be considered a high revenue ACO (as these terms are defined in §425.20), the ACO must take corrective action or terminate its participation under the BASIC track by the end of the current performance year.

Many comments to the December 2018 final rule disagreed with the more aggressive transition of ACOs to performance-based risk. Some also noted that while this may increase ACO performance of those that continue to participate, it could reduce participation overall. CMS observed this with AIM participants, which meaningfully outperformed peer ACOs but then dropped out at an elevated frequency before even attempting to enter the one-sided model (upside-only) portion of the BASIC track glide path. CMS believes this suggests two things:

- While an upside-only participation option with a lower shared savings rate can be a highly effective incentive for smaller, low-revenue ACOs targeted by AIM, such ACOs also likely feel a correspondingly magnified disincentive to accept exposure to even the limited downside risk presented by the current BASIC track glide path.
- Not even superior performance under Track 1 appears to provide enough confidence for such ACOs to consistently move into participation options leading to assumption of two-sided risk.

In response to several commenters' concerns that requiring the rapid assumption of significant levels of risk by ACOs would discourage new participants and impede current ACOs' ability to make patient-centered infrastructure investments that are necessary for successful participation, CMS had stated its commitment to continue to monitor program participation and consider further refinements to the program's participation options. Most commenters on the participation options that were finalized in December 2018 recommended that CMS extend the time an ACO can participate in a one-sided model to 3 performance years, as opposed to the 2 performance years adopted generally under the BASIC track.

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Table 43, reproduced below, shows that 59 percent of the 483 ACOs are in a two-sided model.

TABLE 43: 2022 Shared Savings Program ACO Track Information

ACO Track	ACOs	Percent
One Sided (41% of ACOs)		
BASIC Track Levels A&B	199	41%
Two Sided (59% of ACOs)		
BASIC Track Levels C&D	40	8%
BASIC Track Level E*	98	21%
ENHANCED Track*	146	30%
TOTAL ACOs PY 2022	483	100%

*Qualifies as an Advanced Alternative Payment Model (APM).
Note: Tracks 1, 2, 3 and the Track 1+ ACO Model are no longer applicable as of PY 2022.

In 2020 and 2021, due to the PHE for COVID-19, CMS provided additional participation option flexibilities, allowing ACOs participating in the BASIC track's glide path the option to elect to forgo automatic advancement and "freeze" their participation for PY 2021 and PY 2022 at their PY 2020 and 2021 levels, respectively. CMS reports that 140 out of 157 (89 percent) currently participating ACOs chose to maintain their participation in a one-sided model rather than move to risk for PY 2021, and 103 out of 140 (74 percent) for PY 2022.

CMS believes it would be prudent to provide greater flexibility for ACOs to join the program under one-sided risk and to remain in the program under lower levels of performance-based risk in order to balance CMS' desire to see more ACOs participate under performance-based risk while also working toward the goal of increasing overall Shared Savings Program participation and improving outcomes for beneficiaries. CMS believes it would be appropriate to allow certain ACOs in their first agreement period in the program to maintain participation in a one-sided model (with a lower sharing rate) for a longer period of time, rather than risk having those ACOs leave the program altogether to avoid transitioning to two-sided risk. Even if an ACO does not earn shared savings, ACOs have demonstrated that they are likely saving Trust Fund dollars by modifying their ACO participants' behavior to coordinate care and carry out other interventions to improve quality and financial performance.

CMS is also concerned that the current policy of considering an ACO's status as a high- or low-revenue ACO in determining the participation options available to the ACO may disincentivize certain providers from forming ACOs or joining existing ACOs. CMS also believes ACOs inexperienced with performance-based risk Medicare ACO initiatives, regardless of their status as a high- or low-revenue ACO, may be more likely to participate in the program if they are allowed more time under a one-sided model than is currently allowed.

Proposal for a 5-Year Agreement Period under a One-Sided Model for Eligible ACOs. In light of the foregoing considerations and others described in the preamble, CMS is proposing to allow certain ACOs more time under a one-sided model and more flexibility in transitioning to higher levels of risk and potential reward by modifying the participation options available under the Shared Savings Program. Currently participating ACOs, or ACOs that begin an agreement period in Level A or Level B on January 1, 2023, may elect to maintain their participation at Level A or Level B for the remainder of their current agreement period. Because the annual

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application and change request cycle will begin before the 2023 PFS final rule is issued, CMS will give ACOs currently participating in Level A or B of the BASIC track glide path the opportunity during the change request cycle to indicate whether they are interested in maintaining their participation at Level A or Level B under this proposed policy, should it be finalized.

All other policies proposed in this section would be effective for agreement periods starting on or after January 1, 2024, unless otherwise noted.

CMS proposes to allow an ACO entering the BASIC track's glide path at Level A that is currently at Level A to elect to remain in Level A for all subsequent performance years of the agreement period—if the following requirements are met:

- The ACO is participating in its first agreement period under the BASIC track,
- The ACO is not participating in an agreement period under the BASIC track as a renewing ACO or a re-entering ACO that previously participated in the BASIC track's glide path under §425.600(a)(4), and
- The ACO is inexperienced with performance-based risk Medicare ACO initiatives.[6]

This voluntary election could occur prior to the automatic advancement of the ACO to Level B and would be made in the form and manner and by a deadline established by CMS.

In the case of an ACO that elects to remain in Level A for the entirety of its first agreement period, the ACO generally would be eligible to enter into a subsequent agreement period under the BASIC track's glide path, giving the ACO 2 additional years of one-sided risk. Thus, if an eligible ACO made this election and did not elect faster advancement to a higher level of risk and potential reward, the ACO would have 7 years under one-sided risk. Currently, ACOs inexperienced with performance-based risk Medicare ACO initiatives generally are limited to 2 years under a one-sided model, which ACOs have informed CMS is not enough time before transitioning to risk.

CMS also proposes permitting an ACO that is inexperienced with performance-based risk Medicare ACO initiatives to participate in the BASIC track glide path for a maximum of 2 agreement periods (once at Level A for all 5 performance years and a second time in progression on the glide path). This option is limited in that an ACO that enters an agreement at either Level A or Level B is deemed to have completed one agreement under the BASIC track's glide path and is only eligible to enter a second agreement under the BASIC Track's glide path if the ACO continues to meet the definition of inexperienced with performance-based risk Medicare ACO initiatives and satisfies either of the following:

- The ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track's glide path only one time; or
- For a new ACO identified as a re-entering ACO, the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track's glide path only one time.

[6] CMS notes this would not exclude re-entering former Track 1 ACOs.

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CMS proposes that an ACO determined to be inexperienced with performance-based risk Medicare ACO initiatives but not eligible to enter the BASIC track's glide path may enter either the BASIC track Level E for all performance years of the agreement period, or the ENHANCED track.

CMS proposes to amend the definition of performance-based risk Medicare ACO initiative at §425.20 to include only Levels C through E of the BASIC track, removing the one-sided Levels A and B from the definition. CMS further proposes updating the definitions of inexperienced with performance-based risk Medicare ACO initiatives and experienced with performance-based risk Medicare ACO initiatives to allow for a rolling lookback period of the 5 most recent performance years.

In determining an ACO's eligibility to participate under the proposed new participation options, CMS proposes considering only an ACO's experience with performance-based Medicare ACO initiatives, not the ACO's status as a high- or low-revenue ACO. CMS also proposes to make the ENHANCED track optional for all ACOs, regardless of experience with performance-based risk Medicare ACO initiatives, including high-revenue ACOs.

If an ACO meets the definition of experienced with performance-based risk Medicare ACO initiatives, CMS proposes that the ACO would be permitted to complete the remainder of its current performance year in a one-sided model of the BASIC track, but would be ineligible to continue participation in the one-sided model after the end of that performance year if it continues to meet the definition of experienced with performance-based risk Medicare ACO initiatives and would be automatically advanced to Level E of the BASIC track at the start of the next performance year.

CMS seeks comment on the foregoing proposals for ACO participation options in the Shared Savings Program, as well as potential alternatives detailed in the preamble.

Proposal to Remove the Limitation on the Number of Agreement Periods an ACO can Participate in Level E of the BASIC Track. Currently, there are limitations on how long ACOs may participate (if at all) in the BASIC track, including at Level E, the BASIC track's highest level of risk and potential reward. Some ACOs have reported that they would rather leave the program than be required to move to the ENHANCED track and have requested that CMS make the ENHANCED track optional for ACOs. CMS now believes it would be in the best interest of the program and Medicare FFS beneficiaries to permit eligible ACOs to continue participating under the BASIC track Level E, rather than risk significant numbers of experienced, successful ACOs terminating their participation in the program instead of progressing to the ENHANCED track. CMS proposes that if an ACO is determined to be experienced with performance-based risk Medicare ACO initiatives, the ACO may enter BASIC track Level E for all performance years of the agreement period, or the ENHANCED track. These options would be available without regard to the ACO's status as a high- or low-revenue ACO. CMS also proposes that all ACOs would be permitted to participate indefinitely under the BASIC track Level E, or the ENHANCED track.[7]

[7] This would include ACOs currently in the ENHANCED track or that participate under the ENHANCED track in

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CMS anticipates providing education and offering outreach to ACOs on the available participation options through various methods—including ACO Coordinators, guidance documents, tip sheets, FAQs, and a bi-weekly newsletter.

3. Determining Beneficiary Assignment Under the Shared Savings Program

CMS reviews the evolution of beneficiary assignment to Shared Savings Program ACOs, beginning with the November 2011 rule in which assignment based upon primary care services delivered was established and the initial list of primary care services adopted for that purpose (76 FR 67853). Periodic updates of the list have been made to reflect changing service codes (e.g., addition of chronic care management services) and approaches to beneficiary assignment (e.g., addition of voluntary assignment).

a. Revised Definition of Primary Care Services (§425.400(c))

CMS proposes to add for PY 2023 and subsequent years the following 4 services and provides rationales for adding them to the beneficiary assignment code list. These HCPCS G-codes are proposed for payment under the PFS in sections II.E. and II.F. of the rule where they are discussed in detail. The complete list of codes to be used for Shared Savings Program assignment purposes beginning with PY 2023 is provided at the end of this section.

(1) Prolonged Services

- GXXX2 Prolonged nursing facility evaluation and management service(s) beyond the total time for the primary service, each additional 15 minutes

This code would be added to an initial or subsequent nursing facility visit (CPT codes 99306 and 99310, respectively) for each 15-minute increment once the time spent by the physician or non-physician practitioner (NPP) exceeds 95 minutes for an initial visit or 85 minutes for a subsequent visit. CMS believes it appropriate to add this code to the assignment list because its base codes are already included on the list.

- GXXX3 Prolonged home or residence evaluation and management service(s) beyond the total time for the primary service, each additional 15 minutes

This code would be added to an initial or subsequent home or residence visit (CPT codes 99345 and 99350, respectively) for each 15-minute increment once the time spent by the physician or NPP exceeds the times for these visits plus an additional 15 minutes. The base times for these visits have not yet been finalized. CMS believes it appropriate to add this code to the assignment list because its base codes are already included on the list.

the future. These ACOs would be permitted to enter a new participation agreement under Level E of the BASIC track.

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(2) Chronic Pain Management Services

- GYYY1 Chronic pain management and treatment, monthly bundle

CMS proposes to add this code to the beneficiary service assignment list, believing it to be similar to existing chronic care management and principal care management services (CPT codes 99430 and 99425, respectively) that are already included on the list. CMS also notes that the monthly bundle includes elements very similar to the elements required for these reference codes (e.g., care plan, medication management, care coordination).

(3) Primary Care Service Codes for Shared Savings Program Beneficiary Assignment as Proposed for PY 2023 and Subsequent Years

CPT Codes

- 96160 and 96161 (administration of health risk assessment).
- 99201 through 99215 (office or other outpatient visit for the evaluation and management of a patient).
- 99304 through 99318 (professional services furnished in a nursing facility; services identified by these codes when furnished in a skilled nursing facility are excluded when reported on claims from Federally Qualified Health Centers or Rural Health Clinics).
- 99319 through 99340 (patient domiciliary, rest home, or custodial care visit).
- 99341 through 99350 (evaluation and management services furnished in a patient's home).
- 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code).
- 99421 through 99423 (online digital evaluation and management)
- 99424 through 99427 (principal care management services)
- 99437, 99487, 99489, 99490, and 99491 (chronic care management services)
- 99439 (non-complex chronic care management).
- 99483 (assessment and care planning for patients with cognitive impairment).
- 99484, 99492, 99493 and 99494 (behavioral health integration services).
- 99495 and 99496 (transitional care management services).
- 99497 and 99498 (advance care planning; excluded when provided in inpatient settings).

HCPCS codes:

- G0402 (Welcome to Medicare visit).
- G0438 and G0439 (annual wellness visits).
- G0442 (alcohol misuse screening service).
- G0443 (alcohol misuse counseling service).
- G0444 (annual depression screening service).
- G0463 (services furnished in Electing Teaching Amendment hospitals).
- G0506 (chronic care management).

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- G2010 (remote evaluation of patient video/images).
- G2012 (virtual check-in, 5-10 minutes).
- G2058 (non-complex chronic care management).
- G2064 and G2065 (principal care management services).
- G2212, GXXX2 and GXXX3 (prolonged office or other outpatient evaluation and management services)
- G2214 (Psychiatric collaborative care model).
- GYYY1 and GYYY2 (chronic pain management services)

b. Technical Update to Home and Residence Services (CPT Codes 99341 through 99350)

CMS proposes to incorporate updated CPT guidelines for Home and Residence Services into policies for the Shared Savings Program's primary care service list. The updated guidelines will take effect starting with the CPT 2023 edition to services furnished in assisted living facilities, group homes, custodial care facilities, and residential substance abuse facilities as well as to beneficiary homes. CMS discusses this change more fully in section II.C. of the rule and proposes there to adopt the updated guidelines under Medicare Fee for Service policies for 2023 and subsequent years.

To implement the update, CMS proposes to add a revised list of primary care services at §425.400(c)(1)(vii)(A)(7) for PY 2023 and subsequent years. The revised list will omit prior references to place of service modifier 12 associated with CPT codes 99341-99350, as place of service 12 would no longer describe the beneficiary group receiving these services.[8]

c. Rural Emergency Hospitals (REHs)

CMS states that it is not proposing to adopt special policies for treatment of services furnished in REHs for purposes of beneficiary assignment under the Shared Savings Program. For assignment purposes, CMS plans to treat services provided in REHs in the same manner as hospital outpatient department services are treated currently by the agency.

d. Using CMS Certification Numbers (CCNs) During Beneficiary Assignment

CMS proposes revisions to the process whereby certain facilities are identified for use in beneficiary assignment, including when a facility's CCN enrollment changes during a Shared Savings Program performance year. The revised process would be applicable starting with PY 2023 and subsequent years for Federally Qualified Health Centers (FQHCs), Rural Health Clinics (RHCs), Electing Teaching Amendment (ETA) hospitals, and Method II Critical Access Hospitals (CAHs). The revised process is described below and would be codified in a new section at §425.402(f).

- Before a performance year starts and periodically during the year, CMS will determine the CCNs for all FQHCs, RHCs, Method II CAHs, and ETA hospitals enrolled under the TIN of an ACO participant. This will include all CCNs with an active Medicare

[8] Place of service 12 is defined by CMS as "location, other than a hospital or other facility, where the patient receives care in a private residence."

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enrollment and all CCNs having a deactivated enrollment status. These CCNs will be used in determining assignment for the performance year.

- CMS will account for CCN enrollment status changes during the performance year as follows:
  - If a CCN with no prior Medicare claims experience enrolls under the TIN of an ACO participant after the ACO certifies its required annual ACO participant list, CMS will consider services furnished by that CCN when determining beneficiary assignment to the ACO if the ACO has elected preliminary prospective assignment with retrospective reconciliation for that year.
  - Services furnished by a deactivated CCN that is listed as an ACO participant when a performance year starts will be considered in determining beneficiary assignment to the ACO for the applicable performance year or benchmark year.
  - For a CCN enrolled under the TIN of an ACO participant when a performance year starts then enrolls under a different TIN during the year, CMS will continue to treat services billed by the CCN as services furnished by the ACO participant it was enrolled under at the start of the performance year for purposes of determining beneficiary assignment to the ACO for the applicable performance year.

CMS believes the proposed process will more accurately capture changes to providers and suppliers that participate in an ACO for a given performance year. CMS emphasizes the importance both to CMS and ACOs of accurate participant, provider/supplier, and attestation lists for use in beneficiary assignment, quality measurement, and compliance activities.

4. Quality Performance Standard and Reporting Requirements (§425.512)

The Shared Savings Program'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. As a result of prior rulemaking, the standard's performance parameters and its associated reporting requirements are set to gradually increase during PY 2023 and PY 2024 before stabilizing for PY 2025 and subsequent years (86 FR 65263). During the transition, ACOs may report either through the CMS Web Interface or using the electronic clinical quality measures (eCQMs) or clinical quality measures (CQMs) of the APM Performance Pathway (APP) of the Merit-based Incentive Payment System (MIPS).[9] Beginning with PY 2025, only the APP reporting mechanism will be available.

In this rule, CMS proposes to add an alternative quality performance standard, base shared savings and loss amounts on sliding scales, and extend the transition period's existing incentive for reporting the APP measures. CMS also proposes to implement a health equity adjustment to ACO quality scores based on beneficiary dual eligibility and residence in a disadvantaged neighborhood. Minor changes are proposed for Web Interface and APP measures. Proposals are made to address interactions between the alternative quality standard and Advanced APM status. CMS invites comment on all proposals, particularly those related to sliding scales for shared

[9] During the transition, if an ACO successfully reports both through the Web Interface and the APP, the higher of its overall quality scores will be used to determine shared savings eligibility and shared savings/loss amounts.

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savings and losses. No changes are proposed to the pay-for-reporting performance standard that applies only to ACOs in the first year of their first Shared Savings Program agreement period (§425.512(a)(2)). CMS discusses a process under consideration for reopening ACO financial performance determinations when quality score errors are subsequently discovered through MIPS targeted reviews. Finally, CMS issues Requests for Information (RFIs) related to beneficiary screening for health-related social needs and about adding questions to the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey.

a. Alternative Quality Performance Standard

CMS proposes to revise the Shared Savings Program's quality performance standard by adding a new, less stringent "alternative" quality performance standard beginning with PY 2023. Under the proposed standard, an ACO achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least 1 of 4 outcome measures in the APP measure set would be eligible for shared savings. The existing standard would be retained (30th percentile for PY 2023), modified to include the proposed health equity adjustment if finalized (described later in the rule and this summary). Proposed performance parameters of the two standards and their associated reporting requirements are shown in Table 51 of the rule and below. The requirement to field the CAHPS for MIPS survey applies to both the existing and proposed alternative quality performance standards.

Each ACO's performance would be assessed using both standards. An ACO meeting the existing standard would continue to be eligible for the maximum shared savings associated with its track and level (e.g., 50% for BASIC Level E). An ACO that meets only the alternative standard would be eligible to receive shared savings but in a lesser, scaled amount than under the existing standard. An ACO that meets neither the existing or alternative standard would be ineligible for shared savings.

CMS makes this proposal to mitigate the "all-or-none" scoring structure of the existing standard (i.e., maximum shared savings or none), allowing more ACOs to realize at least some shared savings. CMS believes that increasing access to shared savings is particularly important during the ongoing transition to higher performance parameters and will facilitate retention and recruitment of ACOs into the Shared Savings Program.

CMS states similar reasons for making a parallel proposal regarding shared losses accrued by ACOs bearing two-sided risk, discussed further below. If those ACOs meet only the alternative quality performance standard, they would be eligible for reduced repayments of their losses. The reduction would be smaller than had the ACO met the existing standard.

Table 51. Proposed Reporting Requirements and Quality Reporting Standard for PY 2023 and Subsequent PYs
(From Table 51 in the rule with formatting modifications)

	PY 2023	**PY 2024**	**PY 2025 and Subsequent Years**
Quality Reporting Requirements	Report 10 Web Interface measures **or** the 3 APP eCQMs/MIPS CQMs; **and** administer CAHPS for MIPS	Same as PY 2023	Report the 3 APP eCQMs/MIPS CQMs; **and** administer CAHPS for MIPS

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Table 51. Proposed Reporting Requirements and Quality Reporting Standard for PY 2023 and Subsequent PYs (From Table 51 in the rule with formatting modifications)			
	PY 2023	**PY 2024**	**PY 2025 and Subsequent Years**
	survey. CMS calculates 2 claims-based measures.		survey. CMS calculates 2 claims-based measures.
Existing Quality Performance Standard Revised to Include the Proposed Health Equity Adjustment	A health-equity adjusted score that is equivalent to or ≥ the **30th percentile** across all MIPS Quality performance category scores (excludes those eligible for facility-based scoring*) **OR** Report 3 APP eCQMs/MIPS CQMs (for each, meet completeness and case minimum requirements); achieve quality performance score equivalent to or >**10th percentile** of performance benchmark on ≥ 1 (of 4) **APP outcome** measures and a score equivalent to or > than the **30th percentile** of performance benchmark on ≥ 1 of 5 remaining APP measures	A health-equity adjusted score that is equivalent to or ≥ the **40th percentile** across all MIPS Quality performance category scores (excludes those eligible for facility-based scoring*) **OR** Report 3 APP eCQMs/MIPS CQMs (for each, meet completeness and case minimum requirements); achieve quality performance score equivalent to or >**10th percentile** of performance benchmark on ≥ 1 (of 4) **APP outcome** measures and a score equivalent to or > than the **40th percentile** of performance benchmark on ≥ 1 of 5 remaining APP measures	A health-equity adjusted score that is equivalent to or ≥ the **40th percentile** across all MIPS Quality performance category scores (excludes those eligible for facility-based scoring*)
Alternative Quality Performance Standard	Fails to meet **2023** criteria above but ACO Quality performance score equivalent to or > than **10th percentile** of performance benchmark on ≥ 1 (of 4) APP outcome measures would allow shared savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality performance score	Fails to meet **2024** criteria above but ACO Quality performance score equivalent to or > than **10th percentile** of performance benchmark on ≥ 1 (of 4) APP outcome measures would allow shared savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality performance score	Fails to meet **2025** criteria above but Quality performance score equivalent to > than **10th percentile** of performance benchmark on ≥ 1 (of 4) APP outcome measures would allow shared savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality performance score
Quality Performance Standard - Standard is NOT Met	If an ACO (1) does not report any of the 10 CMS Web Interface measures or any of the 3 APP eCQMs/MIPS CQMs **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.	Same as PY 2023	If an ACO (1) does not report any of the 3 APP eCQMs/MIPS CQMs **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.
*Facility-based scoring allows certain clinicians (e.g., pathologists) to be scored using their facilities' Hospital Value Based Purchasing Program results.			

b. Scaled Shared Savings (§§425.605 and 425.610)

Beginning with PY 2023, CMS proposes to adopt a sliding scale approach to calculate shared savings for BASIC and ENHANCED track ACOs that meet the proposed alternative quality

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performance standard but not the existing standard. The sliding scale approach would be agnostic to the ACO's quality data reporting mechanism (Web Interface or APP). The ACO's quality performance score would be multiplied by the maximum sharing rate allowed by the ACO's track and level, as shown below. CMS plans to use the proposed health-equity adjusted quality performance score, described later in the rule and this summary, for the scaled shared savings calculation. An example calculation is described in section III.G.4.b.(2) of the rule.

Proposed scaled shared savings rate = health-equity adjusted quality score x maximum shared savings rate for ACO track and level

CMS notes that a sliding scale approach to shared savings has been used previously in the Shared Savings Program. To maximize the amount received by each ACO eligible for shared savings, however, CMS replaced the sliding scale with the all-or-none approach during CY 2021 PFS rulemaking. The agency states that its proposal to return to a sliding scale is responsive to stakeholder concerns about declining scores caused by the transition to the APP measure set. Under the APP reporting mechanism (1) ACO performance will be compared to all MIPS eligible clinicians rather than only to other Shared Savings Program ACOs, (2) measures include patient data regardless of payer rather than only Medicare beneficiaries, and (3) small differences in MIPS quality score distributions could markedly change the number of ACOs that qualify for shared savings.

In addition to meeting quality standard and reporting requirements, to be eligible for shared savings, an ACO must first meet the minimum savings rate (MSR) requirement for its track and level. CMS later in the rule proposes to enable certain low-revenue ACOs in the BASIC track to share in savings even if the ACO does not meet its MSR. Criteria for such ACOs are proposed in a new provision at §425.605(h) and would apply to ACOs entering a BASIC track agreement period beginning January 1, 2024 or in subsequent years. An ACO that satisfies the specified criteria and meets the quality reporting standard would be eligible to receive shared savings at one-half of the maximum sharing rate for their track and level. The applicable quality standard used would be the existing standard but modified to utilize the proposed health equity-adjusted performance score. The reader is referred to section III.G.5.f(2) of the rule and to the Financial Methodology section of this summary below for further discussion.

c. Scaled Shared Losses (§425.610)

CMS proposes two revisions to the current sliding scale approach to calculating shared losses for Shared Savings Program ENHANCED track ACOs beginning with PY 2023. First, eligibility for the scaled loss approach would be expanded beyond ACOs meeting the existing quality performance standard to include those meeting the proposed alternative quality standard. Second, the shared loss rate calculation would be modified by replacing the current multiplier (MIPS quality performance category points earned ÷ total available points) with the proposed health-equity adjusted quality performance score, as shown below. The track's 75 percent maximum loss rate and 40 percent minimum loss rate would remain unchanged. An example calculation is described in section III.G.4.b.(3) of the rule.

Proposed scaled shared loss rate = 1 – (health-equity adjusted quality score x 75%)

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CMS believes that the proposed changes would make scaled (i.e., smaller) shared losses available to some ACOs that would otherwise face the maximum shared loss rate of 75 percent and would make the formula easier to understand without materially changing the methodology.

d. Interactions Between the Alternative Quality Standard and Advanced APM Status of ACOs

CMS discusses a potential conflict between the proposed alternative standard and the existing criteria for determining Advanced APM status. ACOs in the ENHANCED track and in Level E of the BASIC track that satisfy the existing Shared Savings Program's quality standard also meet the Advanced APM criterion that calls for payment to be contingent upon performance on at least 2 MIPS quality measures, one or more of which must be an outcome measure(s).[10] The APM criterion would not be satisfied by an ACO meeting only the proposed alternative quality performance standard since it requires just one measure. An ACO meeting only the alternative standard could earn scaled shared savings but would no longer qualify as an Advanced APM, and its clinicians would not receive credit towards APM Qualifying Participant status and its associated positive payment adjustments.

CMS notes that the conflict would be eliminated if a change to modify the Advanced APM quality criterion to require only one measure that is also an outcome measure is finalized as proposed in section IV.A.4.a. of the rule. If that proposal is not finalized, CMS plans to consider finalizing an alternative policy that would allow scaled shared savings beginning with PY 2023 and for subsequent years when an ACO (1) scores at or above the 10th percentile on one measure, (2) scores at or above the 30th percentile on a second measure, and (3) one of its two scored measures is an outcome measure. The alternative policy also would satisfy the existing Advanced APM quality criterion and allow the ACO to maintain its Advanced APM status. Concomitantly, if the revised Advanced APM quality criterion is not finalized as proposed, CMS would consider a parallel alternative policy applicable to scaled shared losses incorporating the same 3 elements described for the scaled shared savings policy.

e. Extension of eCQM/MIPS CQM Transition Incentive

CMS proposes to extend the incentive for ACOs to transition from reporting quality data through the CMS Web Interface to using the APP's eCQMs/CQMs measure set. The incentive, currently applicable through PY 2023, allows an ACO to meet the existing quality performance standard by (1) reporting 3 APP eCQMs/MIPS CQMs, meeting completeness and case minimum requirements for each, (2) scoring at or above the 10th percentile on one or more APP outcome measures, and (3) scoring at or above the 30th percentile on one or more of the remaining APP measures. The extension would apply through PY 2024 and for that year would specify scoring at or above the 40th percentile, rather than at the 30th percentile as currently specified.

CMS also requests comment on a related issue. If the MIPS Advanced APM quality criterion is revised as proposed in section IV.A.4.a of the rule (i.e., to require only one measure that is also

[10] Measures not included in the MIPS inventory may satisfy the requirement under certain specified circumstances. See §414.1415(b)(2) and (b)(3).

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an outcome measure), CMS is considering incorporating that change into the ACO quality reporting transition incentive by dropping the incentive's 30th or 40th percentile scoring requirement (for PY 2023 and PY 2024 respectively). The net result would be that an ACO could qualify for the incentive – and thereby meet the quality performance standard – for PY 2023 and PY 2024 solely by (1) reporting 3 APP eCQMs/MIPS CQMs, meeting completeness and case minimum requirements for each and (2) scoring at or above the 10th percentile on one or more APP outcome measures.

The quality standard requirements for PY 2025 and subsequent years as proposed do not interact with the proposed MIPS quality criterion revision. To meet the PY 2025 standard an ACO would be required to (1) report 3 APP eCQMs/MIPS CQMs, meeting completeness and case minimum requirements for each and (2) achieve a health-equity adjusted score that is equivalent to or above the 40th percentile across all MIPS Quality performance category scores (excluding those eligible for facility-based scoring).

f. Health Equity Adjustment

CMS proposes to adopt a health equity adjustment into the Shared Savings Program beginning with PY 2023. The adjustment would be incorporated into calculation of quality performance scores and shared savings and losses and into the extreme and uncontrollable circumstances policy. CMS further proposes that ACO eligibility for the adjustment would be determined by the proportion of assigned beneficiaries that are dually eligible or reside in disadvantaged neighborhoods and would be restricted to ACOs with relatively higher quality performance scores. The adjustment would be implemented through two proposed quality performance score adjusters and be capped at 10 points.

CMS believes that the proposed approach would appropriately award delivery of high-quality care to all patients served by an ACO, incent ACOs to include vulnerable patient groups and providers who treat them, reduce healthcare disparities, and extend accountable care relationships to more Medicare beneficiaries. CMS further believes that this approach avoids potential pitfalls of using risk adjustment methods to advance equity such as masking disparities and setting lower quality of care standards for underserved populations.

(1) Identifying Eligible ACOs

CMS proposes that the health equity adjustment would be available only to ACOs that report using the 3 eCQMs/MIPS CQMs of the APP measure set and meet data completeness requirements for each of these all-payer measures. In addition, the ACO would be required to field the CAHPS for MIPS survey. CMS would continue to calculate scores on two claims-based measures. ACOs reporting quality data only through the CMS Web Interface would not be eligible for the adjustment.

(2) Performance Grouping and Measure Performance Scaler

CMS proposes to link ACO eligibility for the health equity adjustment to performance on all 6 APP measures (eCQMs/MIPS CQM, CAHPS, and claims). ACOs would be divided into thirds, creating top, middle, and bottom "performance groups". Groups would be created independently for each of the 6 measures to capture performance variations within ACOs across measures.

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Performance grouping also would take reporting mechanism into account. ACOs reporting eCQMs would be compared only to other eCQM reporters and ACOs reporting MIPS CQMs would be compared only to other MIPS CQM reporters. Comparisons for the CAHPS and claims-based measures would take into account all ACOs submitting data for those measures.

CMS proposes to assign a value from zero to 4 for each measure for each ACO: a value of 4 for top performers, 2 for middle performers, and zero for bottom performers. The values would be summed into a "measure performance scaler", ranging from 0 to 24 points. CMS also would assign a value of zero for a measure for which the case minimums or sample size is not met by an ACO. However, CMS would still calculate a measure performance scaler using all measures for which complete data are available as long as data for at least the 3 eCQM/MIPS CQM measures are complete. Example calculations for the measure performance scaler are described in section III.G.4.b(7)(f) and Table 47 of the rule.

CMS indicates having considered other performance value assignment distributions and use of a 0/1/2 value set is discussed in detail. CMS states that the chosen 0/2/4 value set maximizes the health equity adjustment points awarded to high-performing ACOs with larger proportions of beneficiaries from underserved populations.

(3) Underserved Multiplier

CMS proposes to award higher positive health equity adjustments to ACOs with larger proportions of assigned beneficiaries from underserved populations. For this purpose, CMS is proposing to use the proportions of dually eligible beneficiaries and those residing in socioeconomically disadvantaged neighborhoods as reflected through the Area Deprivation Index (ADI).[11] The "underserved multiplier" could range between zero and 1 and would be set as the higher of an ACO's assigned beneficiary population that (1) are dually eligible or (2) reside in a census block group with an ADI national percentile rank of 85 or greater. Both the underserved multiplier and the previously described measure performance scaler would be used in calculating an ACO's health equity adjustment.

CMS believes that dual eligibility more closely reflects characteristics of underserved beneficiaries at the individual level (e.g., income) while the ADI more broadly reflects neighborhood level characteristics (e.g., employment, housing) that may influence the healthcare delivered to the neighborhood's residents.[12] As such, CMS sees the two proportions as complementary adjusters indicating potentially underserved status but with some degree of overlap. By proposing to use the higher adjuster's value, CMS seeks to more fully capture important determinants of healthcare outcomes while minimizing beneficiary double-counting due to overlap.

CMS also considered two alternatives: (1) the underserved multiplier is the sum of the dual and high ADI proportions or (2) the proportion of assigned beneficiaries eligible for the Part D low-

[11] The census block-level ADI is based on a measure created by the Health Resources and Services Administration (HRSA) and refined by researchers at the University of Wisconsin.

[12] CMS states that an ADI percentile rank of 85 or greater has been correlated with worse health outcomes such as increased rates of hospitalizations for conditions including heart failure and pneumonia.

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income subsidy (LIS) is added as a third adjuster for consideration – either to replace the dual proportion or used in a three-way comparison of adjuster values to determine the highest value, which would be used. A more detailed discussion is provided in section III.G.4.(7)(a) of the rule. **CMS specifically seeks comment on potential inclusion of the LIS proportion as part of the underserved multiplier.** CMS notes that LIS subsidy eligibility is standardized nationally whereas Medicaid eligibility varies across states. Additionally, CMS notes the ADI represents an all-payer population whereas dual eligibility and the LIS are linked specifically to Medicare as a payor.

(4) Determining Health Equity Adjustment Bonus Points and Health Equity-Adjusted Quality Performance Scores

CMS proposes to apply the health equity adjustment to payment in the form of bonus points added to an ACO's MIPS Quality performance category score (i.e., score for the APP measure set). The bonus points would equal the product of the performance scaler, the underserved multiplier and the performance score, and the sum of the bonus points and the MIPS quality score would be termed the health equity-adjusted quality performance score, as shown below.

Proposed health-equity adjustment bonus points = MIPS Quality performance category score x measure performance scaler x underserved multiplier

Proposed health-equity adjusted quality performance score = MIPS Quality performance category score + health-equity adjustment bonus points

CMS further proposes:

- to cap the health-equity adjustment bonus points at 10,
- to cap the health-equity adjusted quality performance score at 100 percent, and
- to set a floor, such that an ACO with an underserved multiplier of less than 20 percent would be ineligible to receive any bonus points.

CMS estimates that 30 percent of ACOs would have an underserved multiplier above 20 percent and expects that setting a floor of 20 percent would help to direct bonus points towards ACOs caring for significant numbers of underserved beneficiaries, increasing their quality performance scores. CMS anticipates that higher health equity-adjusted scores could enable those ACOs to meet the quality performance standard (or the alternative standard if finalized) and earn shared savings or have their shared losses reduced. Enhanced financial stability could incent these ACOs to remain in the Shared Savings Program and attract to the program new provider groups that care for large numbers of underserved beneficiaries.

(5) Calculation Steps and Examples

In section III.G.4.b(7)(f) of the rule CMS reviews the series of calculations to determine health equity adjustment bonus points and health equity-adjusted quality performance scores and shows examples for each step across a range of ACO characteristics and performances (Tables 47 through 50). The steps followed and the results for example ACO #3 are provided below.

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Step 1: Calculate the measure performance scaler. ACO #3 measure scores fall into the top performing group for 3 measures and the middle group for 3 measures. The ACO is assigned a value of 4 for 3 measures and a value of 2 for 3 measures; when summed, the assigned values total to a measure performance scaler of 18.

Step 2: Calculate the underserved multiplier. ACO #3 has a dual eligible beneficiary proportion of 0.3 and a proportion of beneficiaries residing in census blocks with ADIs of 85 or greater of 0.3. The "higher value" is 0.3. which becomes the underserved multiplier.

Step 3: Calculate the health equity bonus points. Multiply the results of steps 1 and 2. ACO #3 is awarded 5.4 bonus points (18 x 0.3).

Step 4: Calculate the equity-adjusted performance score. Add the bonus points to the MIPS Quality category performance score. For ACO #3, 5.4 bonus points are added to its MIPS quality score of 85.0 to give a health equity-adjusted quality performance score of 90.4 for ACO #3.

CMS describes a plan to include the health equity adjustment calculations and their results for an ACO as part of its financial reconciliation reports package if the ACO has reported data for the APP's eCQM/MIPS CQMs, even if the ACO also reported data through the CMS Web Interface.

CMS notes that an ACO submitting both APP and Web Interface measure data will be assigned the higher of its 2 resulting MIPS quality category performance scores. However, if adding the ACO's bonus points to its APP-based performance score results in an equity-adjusted performance score higher than the Web Interface-based quality score, the higher equity-adjusted score will be used as the ACO's quality performance score for determining shared savings eligibility and calculating shared savings and losses. CMS emphasizes that MIPS quality category scoring for the ACO's clinicians uses the higher of the ACO's APP-based or Web Interface-based scores prior to any bonus point addition (i.e., the equity-adjusted quality score is not used when scoring the MIPS Quality performance category at the individual MIPS clinician level).

(6) Extreme and Uncontrollable Circumstances Policy (§425.512(b))

CMS proposes to specify that the health equity-adjusted quality performance score would be taken into consideration when determining the quality performance score and calculating shared savings/shared loss reductions for an ACO that has been affected by extreme and uncontrollable circumstances. CMS notes, however, that substituting the equity-adjusted score for the unadjusted score would have limited impact because the current extreme and uncontrollable circumstances policy already assigns to an affected ACO a MIPS quality performance category score that is sufficient to qualify for shared savings/shared loss reductions (e.g., 30th percentile across MIPS quality measures for PY 2023).

More specifically, CMS also notes that:

- Per existing policy, an affected ACO would qualify for the maximum shared savings rate for its track and level and that is not changed by proposals in this rule.

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- Per existing policy, an affected ACO on the ENHANCED track and liable for shared losses already receives a shared loss rate scaled by its quality performance and that is not changed by proposals in this rule.
- For an affected ACO eligible to receive a health equity adjustment as provided for by policies proposed in this rule, the bonus points would be calculated and awarded according to those policies if finalized. If the ACO's health equity-adjusted quality score is higher than the quality performance score assigned to it per existing policy, the equity-adjusted score would replace the policy-based score. In practicality, the ACO would qualify for the maximum savings rate with or without the bonus points.
- For an affected ACO on the ENHANCED track and liable for shared losses, receiving bonus points could potentially produce an equity-adjusted performance score that would reduce losses more than would the performance score assigned per policy. The equity-adjusted score would be used to calculate the shared loss reductions.
- An ACO affected by extreme and uncontrollable circumstances that fails to report quality data via the APP, or whose data do not meet completeness or case minimum requirements, by definition would not meet the proposed eligibility criteria for receiving equity bonus points. Therefore, the affected ACO would be assigned its quality score per policy (e.g., 30th percentile across MIPS quality measures for PY 2023).

g. Summary of Proposals

CMS provides its quality standard and reporting proposals arranged by first applicable performance year in narrative form in section III.G.4.(b)(9) and in tabular form as Table 51 (reproduced earlier in this summary). CMS lists its proposals with their associated regulation text changes in section III.G.4.b(7)(h). **The agency also emphasizes several of its requests for comment on specific aspects of its proposals: (1) the measure performance scaler and its associated value assignments, (2) capping the health equity bonus points at 10, (3) setting a minimum ADI proportion above the 85th percentile to be eligible for bonus points, and (4) the alternative methodologies considered for determining the underserved multiplier (e.g., use of the LIS as an underserved indicator variable).**

h. Shared Savings Program Quality Measure and Benchmark Changes

In Table 52, CMS lists the required measures as finalized for PY 2022 for both the CMS Web Interface and APP measure set quality reporting options. For PY 2023, the measures for both options are largely unchanged from those adopted for PY 2022. The Web Interface option will no longer be available starting with PY 2025.

(1) Web Interface Reporting

CMS notes that measure Q110 *Preventive Care and Screening: Influenza Immunization* is being proposed for removal from the MIPS Quality Measure Inventory for all uses except in the Shared Savings Program beginning with PY 2023 (see Appendix 1 Table Group CC for the detailed rationale for removal). The measure will be retained in the Web Interface set for continued use in the Shared Savings Program. Additionally, changes are proposed to all measures in the Web Interface set including Q110. Many changes are technical specification revisions and others

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increase alignment between eCQMs and their corresponding MIPS CQMs. All of the measures, the changes, and rationales for change are described in detail in Appendix 1 Table Group E.

(2) Web Interface Benchmarks

CMS proposes to create benchmarks according to previously established Shared Savings Program policies (found at §425.502(b)) for the measures in the Web Interface set for PYs 2022 through 2024. CMS would accomplish this change by adding new paragraph (a)(6) to §425.512, where the quality performance standard is codified for years beginning on or after January 1, 2021. When use of this measure set by ACOs was extended beyond PY 2021 during CY 2022 PFS rulemaking, CMS inadvertently failed to update the measure benchmarks. Proposing benchmarks now for PY 2022 represents retroactive application of a substantive change and CMS proposes to do so by invoking its authority under section §1871(e)(1)(A) of the Act to apply such changes when failing to do so would not be in the public interest. CMS presents a detailed rationale for using its authority in section III.G.4.c(2) of the rule.

CMS further proposes to score 2 Web Interface measures using flat percentage benchmarks for PY 2022: *Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention* (Q226) and *Preventive Care and Screening: Screening for Depression and Follow-up Plan* (Q134). By so doing, CMS addresses issues of having incorrectly stated during CY 2022 rulemaking that a benchmark would not be created for Q226 and having newly determined that sufficient historical data for benchmarking is lacking for Q134. Policies for applying flat percentage benchmarks are found at §425.502(b)(2). CMS would again apply its authority to make retroactive changes. In support of retroactive change, CMS notes that the proposed changes, if finalized, would increase the number of Web Interface measures on which ACOs could be scored and thereby contribute to their quality performance scores as well as potentially allow them to achieve shared savings. CMS anticipates applying flat percentage benchmarks again for PY 2023 for these 2 measures.

(3) APP Measure Reporting

CMS proposes to retitle the measure *Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS* finalized for PY 2023 to *Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions* and to designate it as quality measure ID# 484. The change is proposed beginning with PY 2023 in order to align measure nomenclature between the Shared Savings Program and the MIPS Quality Inventory. This measure as proposed and the others that would constitute the program's APP measure set for PY 2023 are shown in Table 53 of the rule and below. The set is otherwise unchanged from PY 2022. In the table CMS also identifies the APP outcome measures within the set to facilitate their use to satisfy certain proposed options of the Shared Savings Program's quality performance standard and alternative quality performance standard (shown in Table 51 earlier in the rule and above in this summary).

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Table 53: Proposed APP Measure Set for eCQM/MIPS CQM Reporting for Performance Year 2023 (reproduced in part from the rule)			
Measure ID #	**Measure Title**	**Measure Type**	**Performance Standard Outcome Measure?***
Q321	CAHPS for MIPS Survey	Patient-Reported Outcome	No
Q479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Outcome	Yes
Q484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Outcome	Yes
Q001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	Intermediate Outcome	Yes
Q134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	Process	No
Q236	Controlling High Blood Pressure	Intermediate Outcome	Yes
* Yes = can be used to meet "outcome" provisions of the Shared Savings Program's quality performance standard or alternative quality performance standard			

i. Clarifying Unweighted MIPS Score Utilization for Quality Standard Determinations

When reporting quality data using the APP measure set, Shared Savings Program ACOs must achieve specified quality score percentiles on eCQMs/MIPS CQMs in order to meet the Program's Quality performance standard and receive shared savings (e.g., 40th percentile for PY 2025 and subsequent years). During PY 2022 rulemaking, CMS began providing historical data for the relevant score percentiles to guide ACOs when comparing their anticipated quality scores to the percentiles required for earning shared savings. CMS provides historical values because current year percentiles are not calculable until all MIPS data have been submitted (after the first quarter of the following year).

CMS has discovered that the historical reference values published during CY 2022 rulemaking (86 FR 39274 and 86 FR 65271) were erroneously determined using a weighted rather than unweighted distribution of MIPS Quality performance category scores. The unweighted distribution had been used in prior years' calculations, and CMS clarifies that the unweighted distribution will continue to be used in future years. In Table 54 of the rule, CMS provides corrected percentile values for PYs 2018 and 2019 along with properly calculated values for PY 2020. The table is reproduced below with the addition of the erroneously calculated, previously published values.

Table 54: Historical Unweighted MIPS Quality Performance Category Scores (modified by HPA to include previously published values)				
PY	**30th percentile**		**40th percentile**	
	Incorrect	**Correct**	**Incorrect**	**Correct**
2018	83.9	59.30	93.3	70.80
2019	87.9	58.00	95.7	70.82
2020	No value published	63.90	No value published	75.59

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j. Reopening Initial Determinations of ACO Financial Performance

Timelines for the Shared Savings Program's financial reconciliation process and for the MIPS targeted review process are not fully aligned. CMS generally releases reconciliation reports in August for the prior PY that include determinations of whether ACOs have met the quality performance standard and are eligible for shared savings or responsible for shared losses. CMS states that MIPS performance feedback reports are issued "typically in the summer". The targeted review period during which an ACO can question its quality category score results opens with receipt of its feedback report and lasts for 60 days, so that all targeted reviews may not be completed until as late as November. As a result of timeline mismatch, an ACO might not discover nor CMS be made aware of MIPS feedback errors that affect ACO performance results until well after an ACO's initial financial determination has been made and during which time CMS may have issued a demand letter to the ACO for recoupment of shared losses.

CMS now describes a standardized approach to reopening ACO financial determinations for good cause – errors resulting from timeline mismatch – that is under consideration by the agency. Under this approach:

1) CMS would not set thresholds for error magnitude or number of ACOs affected that could trigger reopening;
2) Upon learning of a MIPS quality score error, CMS would exercise its reopening discretion (see §425.502) to correct errors affecting shared savings eligibility determination or shared savings/loss amounts; and
3) Once having found good cause to make a correction(s), CMS would apply shared savings or loss changes to the ACO's financial reconciliation during the following year.

CMS notes that the reopening process would not defer the obligation of an ACO that has received a demand notice to repay those shared losses within 90 days of being notified. Any over- or underpayments would be addressed in the following year's financial reconciliation.

CMS seeks comment on this clarification of when it would exercise its discretion to reopen for good cause when either an initial determination or a final agency determination regarding an ACO's financial performance needs to be corrected as a result of any corrections made to MIPS Quality performance category scores that affect the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO.

k. Request for Information (RFI): Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health Measures and Future Measure Development

CMS seeks comment on the potential future inclusion of two new measures in the APP Measure set if they first are adopted into the MIPS Measure Inventory for use in the traditional MIPS program.

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Screening for Social Drivers of Health

This process measure is being proposed elsewhere in this rule for inclusion within all of the inventory's specialty measure sets for performance year 2023/payment year 2025 of the traditional MIPS program. It is being specified as a CQM but not as an eCQM at this time. The measure assesses the percentage of adult beneficiaries in a provider's practice who are screened for 5 health-related social needs (HRSNs): food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety. The Measure Applications Partnership (MAP) conditionally supported this measure for rulemaking, and it is not yet endorsed by the National Quality Forum (NQF). The measure as adapted for use in the acute care hospital setting also has been proposed for adoption into the Hospital Inpatient Quality Reporting (HIQR) program for voluntary reporting for CY 2023/FY 2025 payment and mandatory reporting beginning with CY 2024/FY 2026 payment.

Screen Positive Rate for Social Drivers of Health

This structural measure is not being proposed at this time for addition to the MIPS inventory. It has been specified as a CQM but not as an eCQM at this time. It assesses the percentage of screened patients who were screen-positive for each of the 5 HRSNs, so that 5 distinct rates are calculated. The Measure Applications Partnership (MAP) conditionally supported this measure for rulemaking, and it is not yet endorsed by the National Quality Forum (NQF). The measure as adapted for use in the acute care hospital setting also has been proposed for adoption into the Hospital Inpatient Quality Reporting (HIQR) program for voluntary reporting for CY 2023/FY 2025 payment and mandatory reporting beginning with CY 2024/FY 2026 payment.

Besides feedback about adding the two measures described above to the APP measure set for use in the Shared Savings Program, CMS asks additional questions about the measures, listed below.

- How to best implement the measures and how they could further drive health equity and health outcomes under the Shared Savings Program?
- What are the possible barriers to implementation of the measures in the Shared Savings Program?
- What impact would the implementation of these measures in the Shared Savings Program have on the quality of care provided for underserved populations?
- What type of flexibility with respect to the social screening tools should be considered should the measures be implemented? While supporting flexibility, how can CMS advance the use of standardized, coded health data within screening tools?
- Should the measures, if implemented in the future, be considered pay-for-reporting measures?

CMS notes that elsewhere in this rule advance investment payments (prepaid shared savings) are being proposed for Shared Savings Program ACOs that meet specified criteria. One of the

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proposed acceptable uses of the payments would be to support strategies to address patient challenges related to social determinants of health.

L. Request for Information (RFI): Addition of New CAHPS for MIPS Survey Questions

CMS poses questions about several potential changes to the current CAHPS for MIPS survey. Shared Savings Program ACOs must administer the survey in order to meet the program's quality performance standard and to be eligible for shared savings.

Personal Experience with Discrimination During Healthcare Delivery

CMS cites study data from 2019 suggesting that roughly 20 percent of adults have experienced discrimination in the health care system. To further explore this topic, CMS asks for input on adding the question and response choices below to the CAHPS for MIPS survey.

> Question: "In the last 6 months, did anyone from a clinic, emergency room, or doctor's office where you got care treat you in an unfair or insensitive way because of any of the following things about you?"
> Responses: Health condition, disability, age, culture, sex (including sexual orientation and gender identity), and income.

This question is being tested in the Medicare Advantage program. Results from that testing will inform the agency's decision making about proposing this CAHPS change through rulemaking.

Price Transparency

CMS seeks feedback on future CAHPS for MIPS survey questions dealing with price transparency and views such questions as consistent with the goals of the No Surprises Act.[13] The survey currently asks "In the last 6 months, did you and anyone on your health care team talk about how much your prescription medicines cost?" CMS is considering adding a more general question such as whether the patient had talked with anyone on their health care team about the cost of health care services and equipment.

Survey Modification for Specialty Group Application

CMS requests input on two options for modifying the CAHPS for MIPS survey to make it more broadly applicable to specialty groups in addition to primary care groups: (1) shortening the survey by removing items relevant only to primary care providers and using the shorter survey with all practitioner groups, or (2) creating a separate shorter survey version for use in assessing specialist care and maintaining the existing longer survey for use with primary care groups.

[13] Title I, Division BB of the Consolidated Appropriations Act, 2021, Pub. L. 116-133.

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5. Financial Methodology

a. Overview

In this section of the proposed rule, CMS is proposing modifications to the financial methodologies under the Shared Savings Program. It states that its proposals are aimed at encouraging sustained participation by ACOs in the program and removing barriers for ACOs serving medically complex and low-income populations. Specifically, CMS is proposing to:

- Incorporate a prospective, external factor in growth rates used to update the historical benchmark
- Adjust ACO benchmarks to account for prior savings
- Reduce the impact of the negative regional adjustment
- Calculate county FFS expenditures to reflect differences in prospective assignment and preliminary prospective assignment with retrospective reconciliation
- Improve the risk adjustment methodology to better account for medically complex, high-cost beneficiaries and guard against coding initiatives
- Increase opportunities for low revenue ACOs to share in savings

The proposed rule also discusses alternatives to some of the combinations it proposed. It discusses ongoing concerns about the impact of the PHE for COVID-19 on ACOs' expenditures. It proposes to exclude from the determination of Medicare Parts A and B expenditures for purposes of calculations under the Shared Savings Program a proposed new supplemental payment for Indian Health Service and Tribal hospitals and hospitals located in Puerto Rico. It concludes with a discussion of modifications to 42 CFR part 425, subpart G to incorporate the related proposed changes.

b. Statutory and Regulatory Background on Establishing and Updating the Benchmark and Determining Savings

Section 1899(d)(1)(B)(i) of the Act specifies that, in each year of the agreement period, an ACO is eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark under section 1899(d)(1)(B)(ii) of the Act. Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established and updated under the Shared Savings Program. Section 1899(i)(3) of the Act grants the Secretary the authority to use other payment models, including payment models that would use alternative benchmarking and savings determination methodologies, if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under the Medicare program and that the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model.

The rules governing the benchmarking calculations and determination of shared savings and losses are set forth in the regulations at 42 CFR part 425, subpart G. In the November 2011 final rule establishing the Shared Savings Program, CMS adopted policies for establishing, updating,

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and resetting the benchmark at §425.602. The Shared Savings Program's regulations have since evolved to include different benchmarking methodologies, including modifications to §425.602, and the addition of separate benchmarking policies for ACOs entering a second or subsequent agreement period at §425.603. Benchmarking policies applicable to all ACOs in agreement periods beginning on July 1, 2019, and in subsequent years, are specified in §425.601. Calculations related to determination of shared savings and shared losses are specified in §425.605 for ACOs participating under the BASIC track, and §425.610 for ACOs participating under the ENHANCED track (formerly referred to as Track 3).

In the June 2015 final rule, CMS established Track 3, constituting the program's highest level of risk and potential reward (80 FR 32771 through 32781). In the December 2018 final rule, CMS renamed Track 3 the ENHANCED track (see, for example, 83 FR 67841), and established the BASIC track, which includes a glide path with five Levels (A through E) (83 FR 67841 through 67857). The BASIC track's glide path allows eligible ACOs to begin under a one-sided model and incrementally advance to higher levels of risk and reward.

In the May 8, 2020, COVID-19 IFC (85 FR 27578 through 27582), CMS established adjustments to benchmark and performance year expenditure calculations to address the COVID-19 pandemic as specified under §425.611. In the 2021 PFS final rule (85 FR 84771 through 84785), CMS summarized and responded to public comments received on these adjustments, and finalized the regulation at §425.611 with modifications.

Details on the Shared Savings Program's financial methodology and policies to address the impact of COVID-19 are included in Specifications documents.[14]

c. Strengthening Participation by Reducing the Effect of ACO Performance on Historical Benchmarks, Addressing Market Penetration, and Strengthening Incentives for ACOs Serving Medically Complex and High Cost of Care Populations.

(1) Regulatory Background

To establish an ACO's historical benchmark for an agreement period, CMS uses ACO historical expenditures for beneficiaries that would have been assigned to the ACO in the 3 most recent years prior to the start of the agreement period. As the statute requires the use of historical expenditures to establish an ACO's benchmark, the per capita costs for each benchmark year must be trended forward to current year dollars and then a weighted average is used to obtain the ACO's historical benchmark. Section 1899(d)(1)(B)(ii) of the Act also requires that the benchmark shall be updated by the projected absolute amount of growth in national per capita

[14] See Shared Savings and Losses and Assignment Methodology Specifications Version 10 (cms.gov)

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expenditures for Parts A and B services under the original Medicare FFS program. Therefore, in the November 2011 final rule establishing the Shared Savings Program, CMS adopted policies for trending forward expenditures for benchmark year (BY) 1 and BY2 to BY3 dollars (76 FR 67924 and 67925), and for updating the benchmark for each performance year during the ACO's agreement period (76 FR 67925 through 67927).
Over the 10 years since the Shared Savings Program was first established, CMS has used a variety of approaches for determining the trend and update factors to make an ACO's cost target more independent of its own expenditures, including using factors based on national expenditures, regional expenditures, or both.

In the November 2011 final rule establishing the Shared Savings Program, CMS adopted trend and update factor policies at §425.602 based on national FFS expenditures (76 FR 67924 through 67927). It finalized use of a national growth rate in Medicare Parts A and B expenditures for FFS beneficiaries for trending forward BY1 and BY2 to BY3 dollars. It also finalized use of a flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the Medicare FFS program to update the benchmark for each performance year of the agreement period.

In the June 2015 final rule, CMS adopted policies for resetting the benchmark for ACOs entering a second agreement period in 2016 at §425.603(b) (80 FR 32786 through 32796). These policies addressed concerns about the use of an ACO's prior performance years as benchmark years in second and subsequent agreement periods by weighting each benchmark year equally and incorporating an adjustment to account for the average per capita amount of savings generated during the ACO's prior agreement period. CMS refers to this adjustment as a "prior savings adjustment." This adjustment applied only to ACOs entering a second agreement period beginning in 2016 because it subsequently finalized an alternative methodology incorporating factors based on regional FFS expenditures to establish, adjust and update the benchmark for ACOs beginning a second or subsequent agreement period in 2017 and later years.

In the June 2016 final rule (81 FR 37953 through 37991), CMS modified the benchmarking methodology to finalize an approach that incorporated factors based on regional FFS expenditures when resetting (or rebasing) and updating ACO historical benchmarks, as specified in §425.603(c) through (f). It replaced the national trend factor used in the rebasing methodology with a methodology incorporating regional trend factors. This revised rebasing methodology applied beginning in 2017 to determine rebased historical benchmarks for ACOs renewing for a second or subsequent agreement period under the Shared Saving Program.

In the December 2018 final rule (83 FR 68005 through 68030), CMS adopted policies at §425.601 that expanded the use of regional factors in establishing, adjusting, and resetting historical benchmarks to all ACOs, including ACOs in a first agreement period, for agreement periods beginning on July 1, 2019, or in subsequent years. These policies sought to address concerns about ACOs influencing their own regional trends by using a blend of national and regional trend factors to trend forward BY1 and BY2 to BY3 when determining the historical benchmark under §425.601(a)(5) and a blend of national and regional update factors to update the historical benchmark to the performance year under §425.601(b) (83 FR 68024 through

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68030). CMS also established a symmetrical cap on the regional adjustment to the historical benchmark equal to positive or negative 5 percent of the national per capita FFS expenditures for assignable beneficiaries for each enrollment type. CMS also modified the schedule of weights used to phase in the regional adjustment at §425.601(f), to reduce the maximum weight from 70 to 50 percent for all ACOs and to slow the phase-in of weights for ACOs with higher spending than their regional service area.

(2) Overview of Considerations for Modification to the Benchmarking Methodology

CMS proposes a combination of policies to ensure a robust benchmarking methodology that would reduce the effect of ACO performance on ACO historical benchmarks and increase options for ACOs caring for high-risk populations. Specifically, CMS proposes to 1) modify the methodology for updating the historical benchmark to incorporate a prospective, external factor; 2) incorporate a prior savings adjustment in historical benchmarks for renewing and re-entering ACOs; and 3) reduce the impact of the negative regional adjustment. It believes these proposed modifications could serve as "stepping stones" to a longer-term approach to the benchmarking methodology, and they are designed to be consistent with the potential approach for incorporating a methodology for administratively set benchmarks, which is described in the related RFI.

These and the other proposed changes to the Shared Savings Program's benchmarking methodology within this proposed rule, would be applicable to establishing, updating, and adjusting the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.

(3) Incorporating a Prospective, External Factor in Growth Rates Used to Update the Historical Benchmark

CMS proposes to incorporate a prospectively projected administrative growth factor, a variant of the United States Per Capita Cost (USPCC) referred to in the proposed rule as the Accountable Care Prospective Trend (ACPT), into a three-way blend with national and regional growth rates to update an ACO's historical benchmark for each PY in the ACO's agreement period. CMS believes that incorporating this prospective trend in the update to the benchmark would insulate a portion of the annual update from any savings occurring as a result of the actions of ACOs participating in the Shared Savings Program and address the impact of increasing market penetration by ACOs in a regional service area on the existing blended national-regional growth factor.

CMS would calculate a three-way blend as the weighted average of the ACPT (one-third) and the existing national-regional blend (two-thirds) for use in updating an ACO's historical benchmark between benchmark year (BY) 3 and the PY. The ACPT would be projected by the CMS Office of the Actuary (OACT) and would be a modification of the existing FFS USPCC growth trend projections used annually for establishing Medicare Advantage rates, excluding indirect medical education (IME), disproportionate share hospital (DSH) payments, uncompensated care payments, and the proposed new supplemental payment for Indian Health Service (IHS)/Tribal Hospitals and hospitals located in Puerto Rico, and including payments associated with hospice claims to be consistent with Shared Savings Program's expenditure

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calculations. CMS proposes to set the ACPT growth factors for the ACO's entire 5-year agreement period near the start of the agreement period. The ACPT factors would remain unchanged throughout the ACO's agreement period, providing a degree of certainty to ACOs.

CMS considered whether the ACPT component of the blend should express projected growth on a relative basis (as the current two-way national-regional blend operates) or on an absolute (flat) dollar basis. It anticipates that the risk-adjusted flat dollar approach will be more beneficial to ACOs. The flat dollar amounts would be risk adjusted to account for differences in severity and case mix between the ACO's assigned beneficiaries and the national assignable FFS population for each Medicare enrollment type. It is not proposing to adjust the ACPT flat dollar amounts for geographic differences in costs or prices, as it believes that doing so could inadvertently reward higher spending, less efficient ACOs with a higher market share in their regional service area.

CMS illustrates in the proposed rule the four steps it would use to set the annualized growth rate(s) and calculate the ACPT flat dollar amounts(s) that would be included in the three-way blend.

Step 1: Calculate annualized growth rate(s) for agreement period

For step 1, OACT would calculate one or more annualized growth rates for the ESRD population (the ESRD ACPT) and one or more annualized growth rates for the aged/disabled population. These annualized growth rate may either be calculated as a uniform annualized projected rate of growth or as a two or more annualized growth rates over each of the 5 performance years of the 5-year agreement period if CMS determines that a uniform annualized projected rate of growth does not reasonably fit the anticipated growth curve.

Step 2: Express the growth rate(s) for each performance year as flat dollar amounts (the ACPT).

For step 2, CMS would multiply BY3 truncated national per capita FFS expenditures calculated by OACT for the assignable FFS population for a given enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries), by the applicable growth rate to calculate the flat dollar amount of growth for each performance year. Thus, for example, if the truncated national assignable per capita expenditures for a given enrollment type was $13,000, and the projected growth rate for that enrollment type in that year is 5 percent per year, the flat dollar amounts would be:

PY1 flat dollar amount = $13,000 x (1.050 – 1) = $650, and PY5 flat dollar amount = $13,000 x (1.276 – 1) = $3,588251

Step 3: Risk adjust the flat dollar amounts.

In step 3, CMS would multiply the flat dollar amounts for each performance year, for each enrollment type, by the ACO's mean BY3 prospective Hierarchical Condition Category (HCC) risk score for that enrollment type. The risk score used would first be renormalized by dividing by the national mean risk score for the assignable FFS population for that enrollment type identified for the calendar year corresponding to BY3. Risk adjusting the flat dollar amounts would allow for a higher update for ACOs serving a population that is more medically complex

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than the national average. If the ACO's BY3 risk score was 1.025, the risk adjusted flat dollar amounts would be:

PY1 flat dollar amount = $650 x 1.025 = $666, and PY5 flat dollar amount = $3,588 x 1.025 =$3,678

Step 4: Re-express risk adjusted flat dollar amounts as relative factors.

The fourth and final step before calculating the three-way blended update factor would be to re-express the risk adjusted flat dollar amount for each enrollment type on a relative basis such that it can be combined in a weighted average with the current two-way blend. CMS would divide the risk adjusted flat dollar amounts computed in Step 3 for a given enrollment type by the ACO's historical benchmark expenditures for that enrollment type. If the historical benchmark expenditures for the enrollment type were $12,000, the final ACPT portion of the blended update factors for this enrollment type would be:

PY1 final ACPT portion of the blended update factor = ($666 / $12,000) + 1 = 1.056, and PY5 final ACPT portion of the blended update factor = ($3,678 / $12,000) + 1 = 1.306

The values in this step would then be combined with the two-way blend to compute the three-way blended update factor. The ACPT would constitute one-third of the total blend, while the remaining two-thirds would consist of the existing two-way blend.

CMS provides an example that results in a higher benchmark which increases the ACO's potential for shared savings and reduces the potential for shared losses, if applicable. It also notes, however, that incorporating the ACPT into a three-way blended update factor could have the potential for mixed effects.

Implementation of a Guardrail to provide protection for ACOs from larger share losses. To address this issue, CMS proposes a "guardrail" to provide protection for ACOs from larger shared losses (or potentially from the negative implications of financial monitoring) based on an updated flexibility to reduce the impact the prospectively determined ACPT portion of the three-way blend if unforeseen circumstances occur during an ACO's agreement period.

CMS would recalculate the ACO's updated benchmark using the national-regional blended factor (two-way blend). If the ACO generates savings using the two-way blend (but not in the three-way blend), the ACO would neither be responsible for shared losses nor eligible for shared savings for the applicable performance year.

It also acknowledges, however that a variety of circumstances could cause actual expenditure trends to significantly deviate from the projections. CMS would retain discretion to decrease the weight applied to the ACPT in the three-way blend (i.e., different than the one-third, absent unforeseen circumstances). It proposes that it would have sole discretion to determine whether unforeseen circumstances exist that would warrant adjustments to these weights.

Impact of Using a Three-Way Blend on Benchmarks. CMS simulated the potential impact of the three-way blend rather than two-way blend and found that, on average, ACOs were better off

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over the course of the 5-year agreement period and the ACOs benchmark on average increased more. Specifically, CMS observed that, on average, over the 5-year period used in its modeling, about 65 percent of ACOs operating in markets with high Shared Savings Program had a larger benchmark increase under the three-way blend compared with the two-way blend. This approach also benefited ACOs with high percentages of dual-eligibles, disabled populations, and ACOs operating in rural areas.

CMS seeks comment on its proposal to use a three-way blend that incorporates the ACPT to update an ACO's historical benchmark for agreement periods beginning on January 1, 2024, and in subsequent years. It also seeks comment on the specific elements of this approach, including its proposal to calculate the ACPT on a risk adjusted flat dollar basis, to institute a guardrail to protect ACOs, and to retain discretion to adjust the weight applied to the ACPT and the two-way blend in the event of unforeseen circumstances.

(4) Adjusting ACO Benchmarks to Account for Prior Savings

CMS proposes to incorporate an adjustment for prior savings that would apply in the establishment of benchmarks for renewing ACOs and re-entering ACOs, that were reconciled for one or more performance years in the three years preceding the start of their agreement period. It believes that such an adjustment would help to mitigate the rebasing ratchet effect on an ACO's benchmark. Furthermore, CMS believes that returning dollar value to benchmarks through a prior savings adjustment could help address an ACO's effects on expenditures in its regional service area. CMS would adjust an ACO's benchmark based on the higher of either the prior savings adjustment or the ACO's positive regional adjustment. It would also use a prior savings adjustment to offset negative regional adjustments for ACOs that are higher spending compared to their regional service area. Overall, CMS believes that this proposal would help ensure that high performing ACOs have incentives to remain in the program for the long-term.

CMS proposes to use the following steps to calculate the prior savings adjustment:

Step 1: *Calculate total per capita savings or losses in each performance year that constitutes a benchmark year for the current agreement period.* For each performance year CMS would determine an average per capita amount reflecting the quotient of the ACO's total updated benchmark expenditures minus total performance year expenditures divided by performance year assigned beneficiary person years. CMS would apply certain requirements in determining the amount of per capita savings or losses for each performance year. For example, the per capita savings or losses would be set to zero for a performance year if the ACO was not reconciled for the performance year.

Step 2: Calculate average per capita savings. Calculate an average per capita amount of savings by taking a simple average of the values for each of the 3 performance years as determined in Step 1, including values of zero, if applicable. CMS would use the average per capita amount of savings to determine the ACO's eligibility for the prior savings adjustment as follows:

- If the average per capita value is less than or equal to zero, the ACO would not be eligible for a prior savings adjustment. The ACO would receive the regional adjustment to its benchmark.

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- If the average per capita value is positive, the ACO would be eligible for a prior savings adjustment.

Step 3: Apply a proration factor to the per capita savings calculated in Step 2. This would be equal to the ratio of the average person years for the 3 performance years that immediately precede the start of the ACO's current agreement period (regardless of whether these 3 performance years fall in one or more prior agreement periods), and the average person years in benchmark years for the ACO's current agreement period, capped at 1. This ratio would be redetermined for each performance year during the agreement period in the event of any changes to the number of average person years in the benchmark years as a result of changes to the ACO's certified ACO participant list, a change to the ACO's beneficiary assignment methodology selection under §425.400(a)(4)(ii), or changes to the beneficiary assignment methodology.

Step 4: Determine final adjustment to benchmark. Compare the pro-rated positive average per capita savings from Step 3 with the ACO's regional adjustment expressed as a single per capita value by taking a person-year weighted average of the Medicare enrollment type-specific regional adjustment values. As detailed in the proposed rule, CMS would adjust an ACO's benchmark based on the higher of either the prior savings adjustment or the ACO's positive regional adjustment. It would also use a prior savings adjustment to offset negative regional adjustments for ACOs that are higher spending compared to their regional service area.

Tables 55 through 58 present hypothetical examples to demonstrate how the adjustment for prior savings would work in practice. In its simulations using 2020 data, CMS states that no ACOs would receive a lower benchmark and that about 22 percent of all ACOs would receive a higher benchmark under this policy. Among ACOs that receive a higher benchmark, the average net effect on per capita benchmark expenditures would be about $130 measured across each of the four enrollment types.

CMS seeks comment on its proposal to adjust the ACO's historical benchmark for savings generated in the ACO's prior agreement period.

(5) Reducing the Impact of the Negative Regional Adjustment

CMS proposes to institute two policy changes designed to limit the impact of negative regional adjustments on ACO historical benchmarks and further incentivize program participation among ACOs serving high cost beneficiaries. It proposes to reduce the cap on negative regional adjustments from negative 5 percent of national per capita expenditures for Parts A and B services under the original Medicare FFS program in BY3 for assignable beneficiaries to negative 1.5 percent. It also proposes that after the cap is applied to the regional adjustment, to gradually decrease the negative regional adjustment amount as an ACO's proportion of dual eligible Medicare and Medicaid beneficiaries increases or its weighted—average prospective HCC risk score increases.

For negative regional adjustments, CMS also proposes to apply an offset factor based on the following: [A] the ACO's overall proportion of BY3 assigned beneficiaries that are dually eligible for Medicare and Medicaid (including dually eligible ESRD, disabled, and aged

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beneficiaries) and [B] the ACO's weighted average prospective HCC risk score for BY3 taken across the four Medicare enrollment types. Specifically, the offset factor would be calculated as:

Offset factor = [A] + ([B] – 1)

This offset factor would be applied to negative regional adjustments after the negative 1.5 percent cap is applied. The offset factor would be subject to a minimum of zero and a maximum of one. It would be calculated as:

Final regional adjustment = Negative regional adjustment x (1 – Offset factor)

The higher an ACO's proportion of dual eligible beneficiaries or the higher its risk score, the larger the offset factor would be and the larger the reduction to the overall negative regional adjustment. If the offset factor is equal to the maximum value of one, the ACO would not receive a negative regional adjustment (that is, the negative weighted average regional adjustment would be fully offset). If the offset factor is equal to the minimum value of zero, the ACO would receive no benefit from the offset factor.

Table 61 in the proposed rule shows a hypothetical example of how a proposed offset factor applied to negative regional adjustments. In its simulations of this proposed policy, CMS found that for ACOs that had a negative regional adjustment under the current policy such an adjustment would have been reduced or eliminated under the proposed policy. It also benefits ACOs that had positive weighted regional adjustment under the current policy but that had at least one enrollment type with a negative regional adjustment. CMS believes that applying the lower cap and the offset factor at the enrollment type level is more straightforward and will have the opportunity to benefit ACOs that may be serving high risk populations in at least one, but not all Medicare enrollment types.

CMS seeks comment on these proposed changes to the calculation of the regional adjustment for agreement periods beginning on January 1, 2024, and in subsequent years.

(6) Alternatives Options for Addressing Concerns about the Effect of an ACO's Assigned Beneficiaries on Regional FFS Expenditures in Establishing, Adjusting, Updating, and Resetting the ACO's Historical Benchmark

CMS also considered alternative options to the three proposals described above in section III.G.5.c.(3) through (5) that would more directly reduce the effect of the ACO's own beneficiaries on its regional FFS expenditures: (1) removing an ACO's assigned beneficiaries from the assignable beneficiary population used in regional expenditure calculations; and (2) expanding the definition of the ACO's regional service area to use a larger geographic area to determine regional FFS expenditures. These related approaches were policies CMS sought comment in the 2022 PFS proposed rule.

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Alternative 1: Removing an ACO's assigned beneficiaries from the assignable beneficiary population used in regional expenditure calculations

Under this alternative, CMS would exclude an ACO's assigned beneficiaries from the population of assignable beneficiaries in the ACO's regional service area used to determine the regional FFS expenditures used in all benchmarking calculations including trending and updating the benchmark and calculating the regional adjustment. To remove an ACO's assigned beneficiaries from the regional expenditure calculation, CMS would use the mathematical approach described in the CY 2022 PFS proposed rule (86 FR 39292 and 39293), which is premised on per capita risk adjusted FFS expenditures for all assignable beneficiaries in an ACO's regional service area (a) can be interpreted as a weighted average of per capita risk adjusted FFS expenditures for the ACO's assigned beneficiaries (b) and per capita risk adjusted FFS expenditures for assignable beneficiaries in the region who are not assigned to the ACO (c), where the weight on (b) is the ACO's regional market share and the weight on (c) is one minus the ACO's regional market share. Shown as an equation this is:

(a) = [(b) x (ACO's regional market share)] + [(c) x (1 – ACO's regional market share)].

Thus, to remove the ACO's assigned beneficiaries from the regional expenditure calculation, CMS would insert the applicable values for (a), (b), and regional market share (all data elements already computed under the current benchmarking methodology) into the above equation and solve for (c) by rearranging the equation as follows:

(c) = {(a) – [(b) x (ACO's regional market share)]} / (1 – ACO's regional market share).

CMS believes this approach would pose relatively limited operational burden and many commenters responding to its comment solicitation stated that this solution could work well. It remains concerned, however, that such an approach to remove an ACO's assigned beneficiaries from the assignable population could incentivize ACOs to "cherry-pick" healthier, lower-cost patients and could unfairly penalize ACOs that specialize in more medically complex, higher-cost patients, running counter to one of the core dynamics it seeks to address (86 FR 65300 and 65301). CMS is also concerned that this approach would incentivize market consolidation.

CMS states that if it were to finalize this option, it would potentially need to adjust the weights currently used in calculating the regional adjustment to the historical benchmark. This could occur, for example, if an ACO were serving an assigned population that is markedly healthier than other assignable beneficiaries in the ACO's regional service area. CMS is worried that this could potentially lead to a dramatic increase in program costs as higher regional adjustments could translate into higher shared savings payments.

Alternative 2: Expanding the regional service area

The second alternative CMS considered in place of the package of policies that it is proposing would seek to reduce an ACO's influence on expenditures in its regional service area by expanding the ACO's regional service area. CMS notes that while it did not outline a specific approach in the 2022 PFS proposed rule, it sought comment on basing regional expenditure

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calculations on larger geographic areas, such as using State-level data or Core-Based Statistical Area (CBSA)-level data, or a combination of data for these larger geographic areas and county-level data (such as blended county/State expenditures).

MedPAC commented to CMS favoring altering the calculation of regional spending by extending the ACO's regional service area to a larger market area (for example, CBSAs, health service areas, or hospital referral regions) in lieu of removing ACO assigned beneficiaries from the calculation of regional FFS expenditures, noting that expanding an ACO's regional service area would help to reduce an ACO's influence on its regional benchmark calculation without explicitly favoring certain categories of ACOs (for example, historically low spending ACOs). Other commenters also supported expanding the regional service area for the purposes of calculating regional FFS expenditures in cases where ACO market penetration is high – some suggested a threshold of 50 percent.

CMS believes that adopting only this second alternative to expand the regional service area would reduce the impact of an ACO's own expenditures on its regional expenditures without introducing incentives for favorable patient selection or concerns about increased volatility that may result from the first alternative of excluding an ACO's assigned beneficiaries from the population of assignable beneficiaries used to determine regional FFS expenditures. It does not believe, however, that it would be as effective in countering the "ratchet effect" It believes that its proposal to incorporate the ACPT into the growth rates used to update the benchmark would ensure that a portion of the update will remain unaffected by observed FFS spending. Furthermore, it has concerns that use of a market penetration threshold may drive further market consolidation as ACOs seek to meet such a threshold.

It also notes that if it were to finalize this second alternative or a combined approach, there are a number of operational factors that it would need to address with greater specificity, including, but not limited to: what alternative geographic area it would use, whether it would replace county-level data with data based on an alternate geographic area or use a blend, and, if using a blend, at what threshold it would be triggered, and what weights would be applied when aggregating expenditures across geographic areas.

d. Calculating County FFS Expenditures to Reflect Differences in Prospective Assignment and Preliminary Prospective Assignment with Retrospective Reconciliation

Under the current benchmarking methodology, CMS uses risk adjusted county-level FFS expenditures, determined based on expenditures for assignable beneficiaries identified for the 12-month calendar year corresponding to the relevant benchmark or performance year, to calculate factors based on regional FFS expenditures used in establishing, adjusting, and updating the ACO's historical benchmark. CMS believes this approach creates a systematic bias in the calculations using county-level expenditures that favors ACOs under prospective assignment.

To remove the favorable bias and bring greater precision to the calculation of factors based on regional FFS expenditures, CMS proposes to calculate risk adjusted regional expenditures using county-level values computed using an assignment window that is consistent with an ACO's

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assignment methodology selection for the performance year. That is, for ACOs selecting prospective assignment, CMS would use an assignable population of beneficiaries that is identified based on the offset assignment window (for example, October through September preceding the calendar year) and for ACOs selecting preliminary prospective assignment with retrospective reconciliation it would continue to use an assignable population of beneficiaries that is identified based on the calendar year assignment window. CMS is not proposing to change the way it would compute national factors that require identifying assignable populations.

To facilitate modeling of the proposed changes, CMS is making available, through the Shared Savings Program website the following data files: risk adjusted county-level FFS expenditures for 2018-2020 calculated based on an assignable population identified using an offset assignment window; and data files with ACO-specific information on the applicable assignment methodology for the corresponding years.[15]

e. Improving the Risk Adjustment Methodology to Better Account for Medically Complex, High-Cost Beneficiaries and Guard Against Coding Initiatives

Currently, for ACOs in agreement periods beginning on or after July 1, 2019, CMS uses prospective HCC risk scores to adjust the ACO's historical benchmark at the time of reconciliation for a performance year to account for changes in severity and case mix for the ACO's assigned beneficiary population between BY3 and the performance year, subject to a cap of positive 3 percent for the agreement period (referred to herein as the "3 percent cap").

Currently, the 3 percent cap is applied separately for the population of beneficiaries in each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries). That is, any positive adjustment between BY3 and any performance year in the agreement period cannot be larger than 3 percent for any Medicare enrollment type.

CMS developed several options to address concerns raised by stakeholders including, but not limited to, accounting for higher volatility in prospective HCC risk scores for certain enrollment types due to smaller sample sizes and allowing for higher benchmarks than the current risk adjustment methodology for ACOs that care for larger proportions of beneficiaries in aged/dual eligible, disabled and ESRD enrollment types (which are more frequently subject to the cap on risk score growth currently).

The three options that CMS considered would modify the existing 3 percent cap on risk score growth:

1. Account for all changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year prior to applying the 3 percent cap on positive adjustments resulting from changes in prospective HCC risk scores, and apply the cap in

[15] See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram?redirect=/sharedsavingsprogram/

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aggregate across the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible);

2. Apply the 3 percent cap in aggregate across the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) without first accounting for changes in demographic risk scores for the ACO's assigned beneficiary population between BY3 and the performance year; and

3. Allow the cap on an ACO's risk score growth to increase by a percentage of the difference between the current 3 percent cap and risk score growth in the ACO's regional service area, where the percentage applied would be equal to 1 minus the ACO's regional market share.

After consideration of the options, CMS is proposing the first option to modify the existing 3 percent cap on positive prospective HCC risk score growth, such that an ACO's aggregate prospective HCC risk score would be subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year plus 3 percentage points. In other words, CMS would calculate a single aggregate value for the cap equal to the dollar-weighted average growth in demographic risk scores across the four enrollment types plus 3 percentage points. CMS would only apply this cap to prospective HCC risk score growth for a particular enrollment type if the aggregate growth in prospective HCC risk scores, calculated as the dollar-weighted average growth in prospective HCC risk scores across the four enrollment types, exceeds the value of the cap.

To implement the new cap, CMS would follow these steps:

Step 1: Determine demographic risk score growth for each Medicare enrollment type.

Demographic risk score growth is measured as the ratio of the ACO's performance year demographic risk score for an enrollment type to the ACO's BY3 demographic risk score for that enrollment type.

Step 2: Calculate the dollar-weighted average demographic risk ratio across the four enrollment types to obtain a single aggregate dollar-weighted average demographic risk ratio. The dollar weight for each enrollment type would be equal to historical benchmark expenditures for that enrollment type divided by the sum of historical benchmark expenditures across all enrollment types. Historical benchmark expenditures for each enrollment type would be calculated as per capita historical benchmark expenditures for that enrollment type multiplied by the ACO's BY3 assigned beneficiary person years for that enrollment type. The aggregate dollar-weighted average demographic risk ratio would be computed by multiplying the risk ratio for each enrollment type by its respective dollar weight and then summing across the four enrollment types.

Step 3: Calculate the sum of the aggregate dollar-weighted average demographic risk ratio from Step 2 and 0.030. This would represent the aggregate cap.

Step 4: Determine prospective HCC risk score growth for each Medicare enrollment type. Prospective HCC risk score growth would be measured as the ratio of the ACO's performance

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year prospective HCC risk score for that enrollment type to the ACO's BY3 prospective HCC risk score for that enrollment type.

Step 5: Calculate the aggregate growth in prospective HCC risk scores. This step requires calculating the dollar-weighted average prospective HCC risk ratio across the four enrollment types to obtain a single aggregate dollar-weighted average prospective HCC risk ratio, using the same dollar weights and the same approach described in Step 2.

Step 6: Determine if the ACO will be subject to the cap. If the ACO's aggregate dollar-weighted average prospective HCC risk ratio determined in Step 5 is less than the aggregate cap determined in Step 3, no cap would apply to the prospective HCC risk ratio for any enrollment type, even if the prospective HCC risk ratio for a given enrollment type is higher than the aggregate cap. If the ACO's aggregate dollar-weighted average prospective HCC risk ratio determined in Step 5 is greater than or equal to the aggregate cap determined in Step 3, proceed to Step 7.

Step 7: Compare the prospective HCC risk ratio for each enrollment type calculated in Step 4 to the aggregate cap determined in Step 3. If the prospective HCC risk ratio for a given enrollment type is greater than the aggregate cap, the prospective HCC risk ratio for that enrollment type would be set equal to the aggregate cap. If the prospective HCC risk ratio for a given enrollment type is less than or equal to the aggregate cap, no cap would apply to the prospective HCC risk ratio for that enrollment type.

The resulting prospective HCC risk ratios would then be multiplied by the ACO's historical benchmark expenditures for the relevant Medicare enrollment type at the time of reconciliation for a performance year to account for changes in severity and case mix for the ACO's assigned beneficiary population between BY3 and the performance year.

Table 63 in the proposed rule provides a numeric example of this proposed methodology for a hypothetical ACO that is determined to be subject to the cap. Table 64 shows an example whether the hypothetical ACO is not subject to the cap.

CMS' modeling suggests that a majority of ACOs that operate in regions with risk score growth in excess of 3 percent for at least one Medicare enrollment type would have had higher updated benchmark under the proposed policy than the current policy.

CMS seeks comment on the proposed changes to the risk adjustment methodology for agreement periods beginning on or after January 1, 2024. CMS also seeks comment on the two alternatives considered. CMS states that it will consider the comments received on these alternative options along with the comments on its proposed changes to the risk adjustment methodology, and may consider adopting one of these alternatives in place of the proposed approach if it concludes that it would better address the concerns with the current risk adjustment methodology.

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f. Increased Opportunities for Low Revenue ACOs to Share in Savings

To ensure that ACOs do not receive shared savings payments due to normal year-to-year variations in Medicare beneficiaries' claims expenditures, CMS is required by statute to specify a Minimum Savings Rate (MSR) that first must be attained before making shared savings payments. CMS reviews the history of changes to various MSRs and tradeoffs associated with setting a higher MSR. For example, a higher MSR would provide greater confidence that the shared savings amounts reflect real quality and efficiency gains, but could also discourage potentially successful ACOs (especially physician-organized ACOs and smaller ACOs in rural areas) from participating.

CMS proposes to apply a new approach to low revenue ACOs entering an agreement period in the BASIC track beginning January 1, 2024, and in subsequent years—including new, renewing, and reentering ACOs, in order to provide incentives both for new ACOs to join the Shared Savings Program and for existing ACOs to remain in the program.[16] ACOs in the BASIC track that do not meet the MSR requirement but that do meet the quality performance standard (or the proposed alternative quality performance standard described earlier) would qualify for a shared savings payment if the following criteria are met:

- The ACO has average per capita Medicare Parts A and B fee-for-service expenditures below the updated benchmark.
- The ACO is a low revenue ACO at the time of financial reconciliation for the relevant performance year.
- The ACO has at least 5,000 assigned beneficiaries at the time of financial reconciliation for the relevant performance year.

Eligible ACOs that meet the quality performance standard to share in savings at the maximum sharing rate would receive only half of the maximum shared rate (20 percent instead of 40 percent under Levels A and B, and 25 percent instead of 50 percent under Levels C, D, and E). For eligible ACOs that do not meet the quality performance standard required to share in savings at the maximum sharing rate but meet the proposed alternative quality performance standard, the sharing rate would be further adjusted according to that proposal, which would reinstate a sliding scale approach for determining shared savings using the ACO's quality performance score, including the health equity adjustment bonus points (if finalized) described earlier. **CMS seeks comment on this proposal to expand the criteria ACOs can meet to qualify for shared savings under the BASIC track.**

g. Ongoing Consideration of Concerns about the Impact of the Public Health Emergency (PHE) for COVID-19 on ACOs' Expenditures

Due to the COVID-19 PHE, CMS previously made the following changes affecting the Shared Savings Program (including some required by law):

[16] High revenue ACOs in the BASIC track, ACOs below 5,000 assigned beneficiaries at the time of financial reconciliation, and ACOs in the ENHANCED track would not be eligible for this option. CMS acknowledges that this proposal differs from the eligibility criteria for AIPs, which are limited to ACOs that are new to the Shared Savings Program, because the AIP policy is intent on lowering barriers to entry.

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- Offered relief to all ACOs that may have been unable to completely and accurately report quality data for 2019 due to the PHE;
- Allowed ACOs whose current agreement periods expired on December 31, 2020, the option to extend their existing agreement period by 1 year;
- Allowed ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for PY 2021;
- Adjusted certain program calculations to remove payment amounts for episodes of care for treatment of COVID-19, specifically the following:
    - Calculation of 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;
    - Calculation of FFS expenditures for assignable beneficiaries for determining county-level FFS expenditures and national Medicare FFS expenditures;
    - Calculation of Medicare Parts A and B FFS revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track;
    - Calculation of 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 of identifying whether an ACO is a high revenue ACO or low revenue ACO and for determining an ACO's eligibility for participation options; and
    - Calculation or recalculation of the amount of the ACO's repayment mechanism.
- Expanded the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication;
- Suspended Medicare sequestration adjustments;[17]
- Held no ACOs liable for shared losses for performance years 2020 and 2021, as those losses were fully mitigated by the adjustment for "extreme and uncontrollable circumstances," for which the PHE for COVID-19 qualified; and
- Suspended the 2021 application cycle for new applicants.

As a result of forgoing the 2021 application cycle for new applications, agreement periods starting in 2022 are the first agreement periods for which 2020 and 2021 would serve as ACO benchmark years. CMS reviews feedback and potential alternatives for addressing the effects of the PHE on ACO benchmarking calculations. OACT analyses found that sharp declines in spending in 2020 tended to rebound in 2021 such that historical benchmarks averaged across a base period including both 2020 and 2021 would appear to represent a reasonable basis from which to update ACO spending targets going forward.

[17] The sequestration adjustment was phased back in, from April 1 to June 30, 2022, at 1 percent. Starting July 1, 2022, sequestration increased to 2 percent. Fully in effect (2 percent), CMS is required to make a 2 percent reduction to shared savings payments that is applied before applying an ACO's shared savings limit. As a result of the suspension of sequestration in 2020 and 2021, shared savings payments made in 2020 and 2021 were roughly 2 percent higher than they would have been otherwise for ACOs that did not earn shared savings in excess of their shared savings limit.

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CMS believes that the current blended national-regional trend and update factors would be sufficient to address and mitigate the impact of the start of the PHE for COVID-19 on benchmark year expenditures. CMS believes the proposal to utilize a three-way blend of the ACPT/national-regional growth rates to update benchmarks (described earlier in this summary) would further mitigate any potential adverse effects of the PHE on historical benchmarks while also protecting against unanticipated variation in performance year expenditures and utilization resulting from a future PHE. **CMS seeks comment on this analysis regarding the impact of the PHE for COVID-19 on Shared Savings Program ACOs' expenditures.**

h. Proposed Supplemental Payment for Indian Health Service and Tribal Hospitals and Hospitals located in Puerto Rico

CMS currently excludes Indirect Medical Education (IME), Disproportionate Share Hospital (DSH) and uncompensated care payments from ACOs' assigned and assignable beneficiary expenditure calculations because CMS does not want to incentivize ACOs to avoid the types of providers that receive these payments, and for other reasons described in earlier rulemaking. In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28396 through 28398), CMS is proposing to establish a new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico, beginning in FY 2023.

In this proposed rule, CMS would exclude these new supplemental payments (if finalized) from the determination of Medicare Parts A and B expenditures for purposes of calculations under the Shared Savings Program, consistent with the treatment of IME, DSH and uncompensated care payments.[18] However, when calculating ACO participant revenue,[19] CMS proposes to include these new supplemental payments (if finalized), also consistent with the treatment of IME, DSH and uncompensated care payments. **CMS seeks comment on this proposed change to account for the new supplemental payments for IHS/Tribal hospitals and hospitals located in Puerto Rico (if finalized) within the Shared Savings Program.**

i. Organization and Structure of the Regulations text within 42 CFR Part Subpart G; Technical and Conforming Changes

CMS notes that to date it has tended to include the entirety of the benchmarking methodology applicable to ACOs, based on their agreement period start date, within a single section of the regulations (42 CFR part 425 subpart G). It notes, however, there are currently a limited number of unused sections within that range and no remaining sections in sequential order following the existing benchmarking sections. This section discusses how it plans to restructure the regulations to incorporate the proposed modifications to the benchmarking methodology. The technical details of its proposed technical and conforming changes can be found in this section.

[18] If included, they would have affected the determination of benchmark and performance year expenditures.
[19] ACO participant revenue is used for determining whether an ACO is a low-revenue or high-revenue ACO, and for determining the revenue-based loss sharing limits under two-sided models of the BASIC track's glide path.

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6. Reducing Administrative Burden and Other Policy Refinements

CMS proposes 2 burden reduction proposals related to ACO marketing materials and beneficiary notification requirements. Also proposed are refinements to the SNF 3-day rule waiver process and data sharing regulations. All proposals would begin with PY 2023.

a. Requirements for ACO Marketing Materials (§425.310)

CMS proposes to eliminate the requirement for an ACO to submit marketing materials to CMS for review and approval prior to their dissemination and reorganizes the regulation text of the section on Marketing Requirements. CMS notes that only 1 of 241 marketing items undergoing advance review in 2021 was denied. ACOs will remain subject to sanctions (including termination) if they fail to comply with the requirements of the reorganized section.

The reorganized section will continue to require that marketing materials and activities must (1) utilize CMS template language if available, (2) be non-discriminatory, (3) comply with regulations regarding beneficiary incentives at §425.304, and not be materially inaccurate or misleading. CMS also retains its authority to request the submission by an ACO at any time of its marketing materials and will continue to issue written notices to ACOs if materials are disapproved. ACOs and their participants and providers/suppliers will continue to be obligated to discontinue use of disapproved materials.

b. Beneficiary Notification Requirements (§425.312)

CMS proposes to reduce the frequency with which beneficiary information notices are provided to beneficiaries from annually to a minimum of once per agreement period. The notice must be in the form and manner specified by CMS. At the beneficiary's next primary care service visit or no later than 180 days after the notice has been provided, the beneficiary must be given a meaningful opportunity to engage with an ACO representative and to ask questions. The follow-up communication opportunity may be verbal or written but must be tracked and documented by the ACO. Documentation must be made available to CMS upon request. The communication interaction does not create a billable service.

CMS also proposes to clarify requirements for posting of beneficiary notification signage in facilities where ACO participants furnish services. The signage informs beneficiaries of the availability of standardized written notices about (1) the ACO and its participants, (2) the beneficiary's option to deny sharing of claims data that are identifiable at the beneficiary-level, and (3) the option to designate an ACO provider through the voluntary assignment process.

CMS clarifies that signage must be posted in all ACO facilities whether or not primary care services are furnished therein. CMS further clarifies that only primary care facilities must furnish the standardized written notice upon beneficiary request. Clarifications will be codified in a newly proposed and redesignated section at §425.312(a)(2)(i).

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CMS believes the changes are responsive to ACOs' concerns that current notification requirements are redundant and confusing to beneficiaries. CMS also notes its ongoing efforts to improve the clarity and relevance of its template notification materials.

c. SNF 3-day Rule Waiver Process (§425.612)

CMS proposes to streamline the process by which an ACO that bears two-sided risk can request a waiver of the SNF 3-day rule, such that an assigned beneficiary can be discharged to and receive inpatient SNF care without a prior 3-day inpatient hospital stay. The beneficiary must be admitted to a SNF Affiliate of the ACO and the SNF must be rated at 3 stars or higher in the CMS 5-star quality rating system.

To reduce the waiver process burden, CMS proposes to drop the requirement that the ACO submit 3 narratives with its application—communication plan, care management plan, and beneficiary evaluation and admission plan. The ACO would be required to provide to CMS upon request narrative materials about its capacity to manage patients under the waiver if granted. CMS has found that the narrative materials have not added value beyond the information contained in other application documents for use in assessing an ACO's capacity to appropriately and safely implement the waiver. Regulation text changes would be made at §425.612(a)(1)(i)(A).

d. Data Sharing Regulations (§425.702)

CMS proposes to update the regulations that govern data sharing by CMS with ACOs by allowing ACOs operating as organized health care arrangements (OHCA) to request aggregate reports and beneficiary-identifiable claims data reports from CMS.

An OHCA is defined under 45 CFR §160.103 (HIPAA regulations) to include an organized system of health care in which more than one covered entity participates and in which the participating covered entities hold themselves out to the public as participating in a joint arrangement and participate in specified joint activities such as quality assessment and improvement activities and payment activities. CMS notes that joint guidance issued by the Office for Civil Rights and the Office of the National Coordinator for Health Information Technology recognizes that ACOs may operate as OHCAs.

CMS states that operating as an OHCA allows an ACO to (1) share protected health information (PHI) among the covered entities in the OHCA without getting authorization from individuals for purposes of the OHCA's health care operations and (2) share PHI for the health care activities of the OHCA without entering into business associate agreements with each other. CMS also believes that the OHCA structure responds to ACO concerns related to gathering and reporting data on ACO patients who are not Medicare beneficiaries once the required transition to all-payer quality measures (eCQMs/MIPS CQMs) is fully implemented for PY 2025.

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7. Seeking Comment on Incorporating an Administrative Benchmarking Approach into the Shared Savings Program

a. Background on Longer Term Approach to Benchmarking under the Shared Savings Program

In this section, CMS seeks comment on an alternative approach to calculating ACO historical benchmarks that would use administratively set benchmarks that are decoupled from ongoing observed FFS spending. It states that benchmarks are a core policy instrument for providing sufficient incentives for ACOs to enter and remain in the Shared Savings Program, with significant implications on impacts to the Medicare Trust Funds. CMS has observed that the benchmarking methodology for the Shared Savings Program and Innovation Center models may include ratchet effects that reduce benchmarks for successful ACOs and jeopardize their continued participation over multiple agreement periods, resulting in selective participation (including limited participation by inefficient ACOs).

CMS states that there are two ways in which the use of factors based on realized FFS spending (which reflects any ACO spending reductions) can lead to lower benchmarks, which it refers to as "ratchet" effects: (1) downward pressure on an individual ACO's benchmark resulting from the impact of its achieved spending reductions on its historical benchmark expenditures, regional adjustment, and update factor; and (2) downward pressure on benchmarks due to program-wide spending reductions across all ACOs. The first type of ratchet effect occurs at the individual ACO level, when an ACO's own savings reduce its benchmark, which can occur when CMS resets the historical benchmark at the start of the ACO's second or subsequent agreement period. The second type of ratchet effect occurs at the program level, where overall program success can apply downward pressure on ACOs' benchmarks through the method for updating benchmarks each performance year for changes in expenditures between Base Year 3 (BY3) and the performance year. MedPAC and researchers are also examining the Shared Savings Program benchmarking methodology and have noted many of the above concerns that eliminating ratcheting effects is essential for the long-term sustainability of the Shared Savings Program.

The RFI seeks to gather information regarding a potential alternative approach to calculating ACO historical benchmarks that would use administratively set benchmarks that are decoupled from ongoing observed FFS spending.

b. Administratively Established Benchmarks as a Potential Solution to Address Benchmarking Concerns

In this section, CMS describes and seeks comment on a direction for future benchmarking that is designed to create a sustainable pathway for long-term program savings for both ACOs and CMS and to address interested parties' concerns around ratcheting. Within this section, CMS provides an overview of and discusses details of key components of this approach.

This approach involves separating benchmarking update factors from realized FFS expenditure growth through the implementation of a prospective, administratively set annual growth rate to update benchmarks. Under this approach, benchmarks would be allowed to rise above realized

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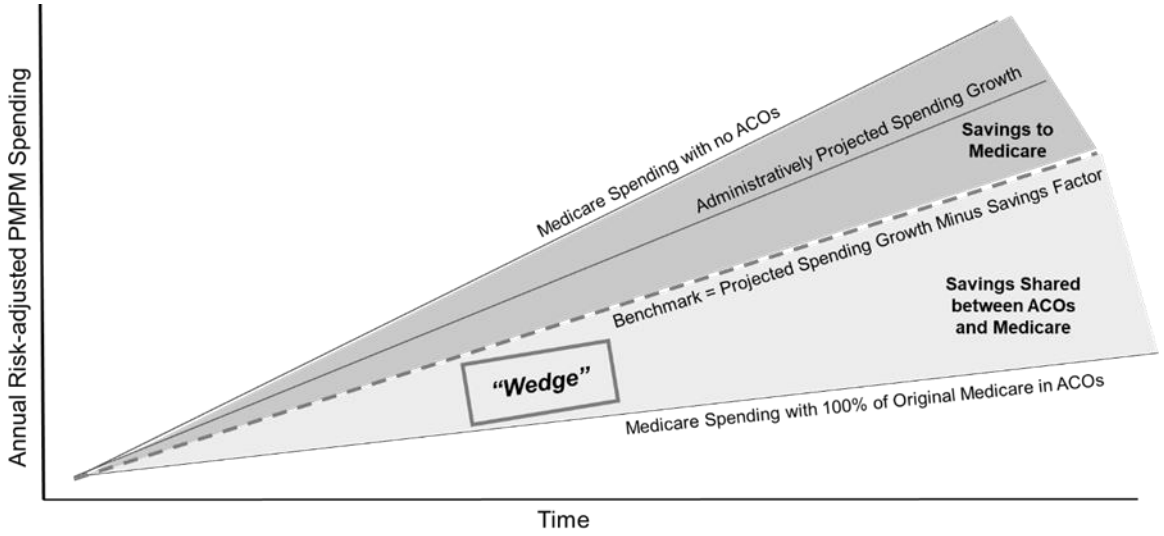
FFS expenditure growth as ACOs generate savings, allowing ACOs to retain more of their savings and thus strengthening incentives to participate and achieve savings. Over time, use of this administratively set growth rate would allow for a wedge to accrue between average benchmarks and realized spending reductions, offering greater and more sustainable savings opportunities over the long-term for both Medicare and ACOs. Importantly, average benchmark growth would only exceed realized FFS spending growth to the extent that ACOs reduce spending, such that benchmarks remain at or below FFS spending levels projected in the absence of ACO participation. A graphic depiction of administratively-established benchmarking is provided in Figure 3 in the proposed rule (reproduced below).

Figure 3: Illustrative Example of Administratively-Established Benchmarking Approach



CMS believes that an administrative set benchmarking approach also offers a path for converging benchmarks gradually towards a common risk-adjusted rate in each region, which it anticipates would mitigate selective participation and improve the savings potential of the program. As long as ACOs are generating savings collectively, CMS believes that this approach would allow all ACOs a chance to earn shared savings while reducing overall spending relative to projections and protecting the Trust Funds. In addition, benchmarks that exceed FFS spending would give ACOs flexibility to meet beneficiary needs through alternative modes of care such as virtual care or care management programs that have not traditionally been reimbursed under FFS.

CMS seeks comment on these concepts and on the design of an administratively established benchmarking methodology. It provides more details on its approach in subsequent sections of the proposed rule. It also welcomes comments on the stages for implementing such an approach within the Shared Savings Program, particularly on an initial convergence phase and a post-convergence phase, and any other considerations related to this approach that it has not addressed in this proposed rule. It also seeks comment on any additional modifications to the design of the Shared Savings Program that should be considered in conjunction with administratively set benchmarks.

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CMS states that establishing administratively established benchmarks would require it to use its authority under section 1899(i)(3) of the Act. This requires that the alternative payment methodology will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures. **CMS seeks comment on the extent to which the use of administratively set benchmarks might have the potential to improve the quality and efficiency of care furnished to Medicare beneficiaries and any anticipated impact on Medicare expenditures.**

c. Establishing an Administrative Benchmark Update Factor

(1) Overview

Under the administratively-established benchmarking concept, CMS would continue to utilize an ACO's historical FFS expenditures to establish the ACO's historical benchmark. It would modify the existing methodology to fully remove negative regional adjustments to the benchmark, but otherwise retain much of the existing methodology. CMS describes its approach more fully in the subsequent sections.

(2) Use of Accountable Care Prospective Trend in the Benchmark Update

CMS is considering an approach that would transition the proposed three-way blend between the prospective Accountable Care Prospective Trend (ACPT) and retrospectively determined regional and national growth rates (as described in section III.G.5.c. of this proposed rule) to an entirely prospectively set trend. For this trend, OACT would calculate an ACPT, based on a modification of the existing USPCC growth projections used annually for establishing Medicare Advantage rates. It believes that an ACPT with some additional modifications could serve as the core component of the administratively set benchmark update under the longer-term approach.

CMS is considering an approach under which it would establish an ACPT every 5 years which would apply during that 5-year window. It is considering maintaining separate projections within the ACPT for price growth, volume/intensity growth, and demographic factors (with potential exceptions for certain service types such as Part B drugs, which are not currently projected using disaggregated growth assumptions). CMS states that it would also need to establish a process for considering additional factors when recalculating the ACPT prospective update factor every 5 years.

CMS seeks comment on these considerations for calculating an ACPT to be used as an administratively set benchmark update factor. It seeks comment on the 5-year intervals for establishing an ACPT, and alternative approaches that would tie the ACPT to an ACO's agreement period. It also seeks comment on approaches to accounting for price growth and demographic factors versus volume/intensity and considerations for guardrails to protect against projection error. Finally, it seeks comment on approaches to updating the ACPT that would ensure it does not overly reflect ACOs' collective impact on spending.

(3) Discount Factor

CMS believes that under its approach there would need to be a period of gradual convergence in spending between efficient and inefficient ACOs. Its approach would be to subtract a modest

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annual discount factor from the fixed 5-year ACPT growth trend based on the relative efficiency of the ACO. For example, if the projected ACPT trend was 5.1 percent annual growth, an ACO with a 0.2 percent discount factor would have a benchmark update factor based on a 4.9 percent annual growth rate (5.1 percent minus 0.2 percent).

To determine what discount would be applied to an ACO's update factor, it would calculate a measure of the ACO's regional efficiency. CMS would compare the ACO's historical spending (the weighted-average spending for the ACO in benchmark year 3) to a regional benchmark (the weighted-average regional FFS expenditures for benchmark year 3). If an ACO's historical spending was greater than its regional benchmark, CMS would apply a discount to the amount of the benchmark update, scaled such that a larger discount is applied for ACOs with increasingly higher spending (less efficient) compared to their regional benchmark. No discount would be applied to the update amount for ACOs with spending 2 percent or more below their regional benchmark. The discount would vary according to the regional efficiency of each participating ACO but, importantly, would not grow if an ACO successfully lowers spending. The calculation would also take into account changes in composition of ACO participant TINs during an agreement period.

CMS seeks comment on this approach for calculating and applying a discount factor in determining the amount of an ACO's benchmark update. It seeks comment on the intervals of the discount described, and alternative approaches such as use of a sliding scale in determining the discount amount. It also seeks comment on approaches to ensuring the discount is reflective of the ACO's regional efficiency, including the approach of recalculating the discount factor to reflect changes in an ACO's regional efficiency as a result of changes in the ACO's composition during its agreement period.

(4) Removal of Negative Regional Adjustments to the Benchmark

In the administratively-established benchmarking concept, CMS would no longer apply negative regional adjustments to the benchmark, although positive regional adjustments would remain. Under this approach, ACOs with higher-than-average historical spending would begin with a benchmark calculated solely using their historical experience. It is also considering approaches for addressing a potential concern that efficient ACOs would be disincentivized from adding less efficient providers and suppliers as ACO participants because it would reduce their regional adjustment. One approach would be to scale an ACO's initial, larger positive regional adjustment based on the overlap in beneficiaries that would have been aligned to the ACO using the ACO's initial ACO participant list and its updated ACO participant list.

CMS seeks comment on this approach, and considerations related to removing the negative regional adjustment in establishing the ACO's historical benchmark under an administratively- established benchmark approach. It also seeks comment on considerations for limiting disincentives for efficient ACOs to add less efficient providers and suppliers.

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(5) Detailed Administratively-Established Benchmark Update Calculation

CMS seeks comment on the step-by-step example of the administratively-established benchmark:

Step 1: Calculate the historical benchmark according to the existing Shared Savings Program benchmarking methodology, without applying negative regional adjustments.

Step 2: Risk-adjust the historical benchmark to account for changes in severity and case mix between BY3 and the performance year for each enrollment type.

Step 3: Apply the update factor to the risk-adjusted historical benchmark for each enrollment type, calculated as follows:

++ Start with the overall OACT-projected Shared Savings Program ACPT 5-year projected trend applicable for the ACO based on the start of its agreement period and the performance year for each enrollment type. The update rate over an agreement period may include ACPT projected trends from more than one 5-year period if the ACO's agreement period does not align with the 5-year cycle for ACPT calculation.

++ Apply the average projected trend based on the number of years between BY3 and the performance year.

++ Apply any retrospective adjustments to the trend based on divergence between the price and demographic components of the ACPT projected trend and observed price trends and demographic changes. This retrospective adjustment would be calculated annually after the end of each performance year only for the price and demographic components (no such adjustment would be made for the volume-intensity component).

++ Subtract the relevant discount factor (as per the examples in Table 70, based on the regional efficiency of the ACO in BY3) from the adjusted trend for each year between BY3 and the performance year to determine the ACO's trend percentage.

++ Multiply the ACO's trend percentage by the average national ACPT value for assignment eligible beneficiaries (adjusted to reflect the ACO's relative risk in each eligibility category) to determine the flat dollar update amount.

++ Apply any guardrails as described in section III.G.7.c.(2) of this proposed rule.

++ Add the flat dollar update amount to the ACO's risk-adjusted historical benchmark for the applicable enrollment type.

Step 4: Calculate a single per capita benchmark amount by taking a weighted average across each enrollment type.

d. Convergence to Regional Benchmarks; Post-Convergence Phase

CMS believes that ultimately, this administratively-established benchmark approach would be partially intended to drive ACOs towards regional spending convergence. It believes that this

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post-convergence phase would completely eliminate ratcheting effects by removing rebasing and would also decouple benchmarks from an ACO's historical spending, thereby creating a sustainable benchmarking approach that would support high ACO participation levels and reward ACOs for increased efficiency. The convergence phase would be intended to converge benchmarks toward some level above realized spending, but below predicted spending absent ACOs, assuming ACOs generate savings. It anticipates that this convergence phase will last between 5-10 years, depending on participation rates and the pace of spending convergence within regions. If the convergence phase takes longer than 5 years, CMS states that it would need to address the potential rebasing effects for ACOs renewing for subsequent agreement periods under the new benchmarking approach.

CMS seeks comment on—

- Considerations for the design of a regionally consistent benchmarking approach, including how to set fair and accurate risk-standardized benchmarks, the process for annual updates to regional rates, and how to distinguish between enrollment types.
- Considerations for the required conditions and timing for reaching this post-convergence phase with the use of regionally consistent benchmarks, as well as incentives to promote ACO spending convergence within a region.
- Approaches to addressing rebasing effects for renewing and re-entering ACOs in subsequent agreement periods during the convergence phase.
- Considerations for converging to nationally consistent spending versus regionally consistent spending.

e. Request for Comment on Addressing Health Equity Through Benchmarking

CMS states that benchmarks based on historically observed spending may be inequitable to the extent that historical patterns reflect existing inequities in both access to care and the provision of care. It is interested in considering how direct modification of benchmarks to account for existing inequities in care can be used to advance health equity. Direct increases to benchmarks for historically underserved populations would grant additional financial resources to health care providers accountable for the care of these populations, and may work to offset historical patterns of underspending that influence benchmark calculation.

CMS discusses the ACO REACH health equity benchmark adjustment as an example to address inequity in benchmarks calculated primarily using historical expenditures, where historical underspending for underserved beneficiaries informs benchmarks. It believes that these and other approaches could be employed to preserve (if not expand) existing payment differentials that set payment higher for certain providers. Equity-motivated benchmark adjustments could be implemented, for example, to support additional funding for safety net providers (for example, CAHs, RHCs, and FQHCs). In other cases, add-on payments, such as DSH and IME, might continue to be carved out of ACO benchmarks and performance year expenditures, as they are now. **CMS seeks comment on other policy adjustments that should be considered for benchmark setting in the post-convergence phase. This includes:**

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- Approaches, generally, to addressing health inequities via the benchmark methodology for the Shared Savings Program, and specifically to incentivize ACOs to serve historically underserved communities.
- Considerations for what data would need to be collected on Medicare beneficiaries and their communities (for example, need for and access to health care providers, transportation, and social services) and what factors should be considered to identify underserved communities and adjust ACO benchmarks.
- Considerations for including a health equity benchmark adjustment in the Shared Savings Program in the near term comparable to the equity adjustment being tested within the ACO REACH Model.
- Considerations for addressing health inequities in the context of the benchmarking concept outlined in this section of this proposed rule.
- Considerations for monitoring and program integrity tools that would track the use of any health equity benchmark adjustments for the intended purposes.
- Considerations for whether benchmark adjustments for ACOs that include CAHs, RHCs, FQHCs, and REHs as ACO participants would improve care for rural and underserved populations and increase participation by these providers and suppliers in the Medicare Shared Savings Program.

8. Impact on Medicare Shared Savings Program

CMS notes that its proposed policies are designed to reverse recent trends where participation has plateaued in the Shared Savings Program, higher spending populations are increasingly underrepresented in the program, and access to ACOs appears inequitable. It believes that the overall increase in shared savings payments to ACOs transitioning to the ENHANCED track appears to be driven largely by favorable regional benchmark adjustments and the track's higher sharing rate. Without modifications, CMS believes that the program is at high risk of increasing overall Medicare spending over the coming decade. Its new proposals are designed to increase program participation for new ACOs through advance investment payments to promote health equity and provide ACO's greater choice in the pace of progression to performance-based risk. It also believes that reducing the cap on negative regional adjustments to high spending ACO benchmarks and offering eligible ACOs a shared savings-only BASIC track participation option for a full 5-year agreement period is expected to significantly re-engage participation for ACOs serving high-cost beneficiaries. This is particularly true for low revenue physician led ACOs for whom a 40 percent sharing rate is a strong incentive for efficiency even absent downside risk.

The proposed rule changes are estimated to reduce overall program spending by $14.8 billion over 12 years relative to the $4.2 billion cost anticipated for the trajectory of the program at baseline, or $10.6 billion in absolute terms relative to a baseline without a Shared Savings Program in FFS Medicare (See Table 142, reproduced below). The impact estimate ranges from a reduction of $8.2 billion to a reduction of $21.4 billion at the 10th an 90th percentiles. CMS anticipates that about 80 percent of advance investment payments are anticipated to be recovered from shared savings payments by the middle of the second agreement period after an initial

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investment of $210 million. It also estimates that approximately $60 million in net savings for 2023 is projected for retaining existing higher-spending ACOs that would have otherwise dropped out if not offered the ability to remain in one-sided risk for the remainder of their current agreement period.

Table 142: Proposed Rule Projected Impact Relative to Current SSP Baseline (Financial Impacts in $Millions)

Program Year	ACO Participation	ACO Benchmark	Claims	Net ACO Sharing	Advance Investment Cash Flow*	Comb. Fed Impact
2023	34	10,940	-80	20	N/A	-60
2024	128	40,040	-490	70	210-70	-420
2025	140	43,490	-760	-200	-40	-960
2026	137	44,110	-950	-120	-20	-1,070
2027	138	45,800	-1,170	-70	-10	-1,240
2028	143	49,060	-1,370	-40	-10	-1,410
2029	155	54,930	-1,700	-10	-10	-1,710
2030	146	53,700	-1,990	310	-10	-1,680
2031	144	55,210	-2,110	310	0	-1,800
2032	144	57,130	-2,100	220	0	-1,880
2033	138	56,820	-2,120	250	0	-1,870
2034			-670	-90	0	-760
12Y Total			**-15,510**	**650**	**40**	**-14,810**
Low (10th Ptile)				-3,710		-21,410
High (90th Ptile)				820		-8,200
*Total advance investment payments in 2024 shown with first year repayment amount in same row for 2024						

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