de: 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 425

[CMS-1799-P]

RIN 0938-AV20

Medicare Program: Mitigating the Impact of Significant, Anomalous, and Highly Suspect Billing Activity on Medicare Shared Savings Program Financial Calculations in Calendar Year 2023

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule addresses policies for assessing performance year (PY) 2023 financial performance of Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs); establishing benchmarks for ACOs starting agreement periods in 2024, 2025, and 2026; and calculating factors used in the application cycle for ACOs applying to enter a new agreement period beginning on January 1, 2025, and the change request cycle for ACOs continuing their participation in the program for PY 2025, as a result of significant, anomalous, and highly suspect billing activity for selected intermittent urinary catheters on Medicare Durable Medical Equipment, Prosthetics, Orthotics & Supplies (DMEPOS) claims. Under the Shared Savings Program, providers of services and suppliers that participate in ACOs continue to receive traditional Medicare fee-for-service (FFS) payments under Medicare Parts A and B, but the ACO may be eligible to receive a shared savings payment

if it meets specified quality and savings requirements. ACOs participating in two-sided models may also share in losses.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by July 29, 2024.

ADDRESSES: In commenting, please refer to file code CMS-1799-P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically*. You may submit electronic comments on this regulation to **http://www.regulations.gov**. Follow the "Submit a comment" instructions.

2. *By regular mail*. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1799-P,
P.O. Box 8016,
Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail*. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1799-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT: Richard (Chase) Kendall, (410) 786-1000, or *SharedSavingsProgram@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment

period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at *https://www.regulations.gov/.*

CPT (Current Procedural Terminology) Copyright Notice

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I. Background

A. Statutory Background on Shared Savings Program Financial Calculations

Section 1899 of the Social Security Act (the Act) (42 U.S.C. 1395jjj), as added by section 3022 of the Patient Protection and Affordable Care Act (Pub. L. 111-148, enacted March 23, 2010), establishes the general requirements for payments to participating Accountable Care Organizations (ACOs) in the Shared Savings Program. Specifically, section 1899(d)(1)(A) of the Act provides that providers of services and suppliers participating in an ACO will continue to receive payment under the original Medicare fee-for-service program under Parts A and B in the same manner as they would otherwise be made. However, section 1899(d)(1)(A) of the Act also

provides for an ACO to receive payment for shared savings provided that the ACO meets both the quality performance standards established by the Secretary and demonstrates that it has achieved savings against a benchmark of expected average per capita Medicare FFS expenditures. Additionally, section 1899(i) of the Act authorizes the Secretary to use other payment models in place of the one-sided model described in section 1899(d) of the Act. This provision authorizes the Secretary to select a partial capitation model or any other payment model that the Secretary determines will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures. We have used our authority under section 1899(i)(3) of the Act to establish the Shared Savings Program's two-sided payment models (see for example, 80 FR 32771 and 32772, and 83 FR 67834 through 67841) and to mitigate shared losses owed by ACOs affected by extreme and uncontrollable circumstances during performance year (PY) 2017 and subsequent performance years (82 FR 60916 and 60917, 83 FR 59974 through 59977), among other uses of this authority described elsewhere in this proposed rule.

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. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO. This benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate and updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare

FFS program, as estimated by the Secretary.

In past rulemaking, we have used our authority under sections 1899(d)(1)(B)(ii) and 1899(i)(3) of the Act to establish adjustments to the benchmark and program expenditure calculations, respectively, to exclude certain Medicare Parts A and B payments. In the November 2011 final rule (76 FR 67920 through 67922), we adopted an alternate payment methodology that excluded Indirect Medical Education (IME) and Disproportionate Share Hospital (DSH) payments from ACO benchmark and performance year expenditures due to concerns that the inclusion of these amounts would incentivize ACOs to avoid referring patients to the types of providers that receive these payments. In the Calendar Year (CY) 2023 Physician Fee Schedule final rule (87 FR 69954 through 69956), we excluded new supplemental payments to Indian Health Service/Tribal hospitals and hospitals located in Puerto Rico consistent with our longstanding policy to exclude IME, DSH and uncompensated care payments from ACOs' assigned and assignable beneficiary expenditure calculations. In the interim final rule with comment period entitled "Medicare and Medicaid Programs; Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program" which was effective on May 8, 2020, and appeared in the May 8, 2020 **Federal Register** (85 FR 27550) (hereinafter referred to as the "May 8, 2020 COVID-19 IFC"), we established a methodology to adjust Shared Savings Program financial calculations to account for the COVID-19 Public Health Emergency (85 FR 27577 through 27582). Specifically, we established a methodology that would exclude all Medicare Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment of COVID-19 to prevent distortion to, among other calculations, an ACO's benchmark and program expenditure calculations.

B. Background on Significant, Anomalous, and Highly Suspect Billing Activity in Calendar Year 2023

Recently, ACOs and other interested parties have raised concerns about an increase in billing to Medicare for selected intermittent urinary catheter supplies on Durable Medical Equipment, Prosthetics, Orthotics & Supplies (DMEPOS) claims in CY 2023, alleging that the increase in payments represents fraudulent activity (the "alleged conduct"). Numerous ACOs have alerted the Centers for Medicare & Medicaid Services (CMS) to potential impacts on their PY 2023 expenditures because of the increased catheter billings.

As of the time of this proposed rule, our investigation into the matter is ongoing, and we have taken initial actions in response. We have made referrals to law enforcement, recouped improper Medicare payments, and terminated certain suppliers from the Medicare program. CMS continues to adapt its monitoring, investigative targeting, and data analytics programs to prevent future fraud, waste, and abuse. CMS also continues to work closely with the Department of Health and Human Services Office of Inspector General and Department of Justice, as well as our Uniform Program Integrity Contractors, to investigate health care fraud activities that exploit our Federal program, such as those involving urinary catheter supplies.

The observed DMEPOS billing volume for intermittent urinary catheters in CY 2023 represents significant, anomalous, and highly suspect (SAHS) billing activity. Generally, this means that a given HCPCS or CPT code exhibits a level of billing that represents a significant claims increase either in volume or dollars (for example, dollar volume significantly above prior year, or claims volume beyond expectations) with national or regional impact (for example, not only impacting one or few ACOs) and represents a deviation from historical utilization trends that is unexpected and is not clearly attributable to reasonably explained changes in policy or the supply or demand for covered items or services. The billing level is significant and represents billing activity that would cause significantly inaccurate and inequitable payments and repayment obligations in the Shared Savings Program if not addressed.

Current Shared Savings Program regulations, codified at 42 CFR part 425, do not provide a basis for CMS to adjust program expenditure or revenue calculations to remove the impact of

SAHS billing activity such as that arising from the alleged conduct in advance of issuing an initial determination. CMS may reopen an initial determination or a final agency determination and issue a revised initial determination at any time in the case of fraud or similar fault, and not later than 4 years after the date of the notification to the ACO of the initial determination of savings or losses for the relevant performance year for good cause (§ 425.315). This does not allow for CMS to address SAHS billing activity, which must be addressed prior to conducting financial reconciliation, which is an initial determination, to prevent significant inequity and inaccurate payment determinations.

We share the concerns recently raised by some ACOs and other interested parties that SAHS billing activity surrounding the selected codes for intermittent urinary catheters would impact Shared Savings Program calculations for PY 2023 and we are also concerned about the impact on other program calculations based on CY 2023 data. Specifically, we are concerned that absent mitigation measures, this SAHS billing activity would inflate Medicare Parts A and B payment amounts, including:

- PY 2023 reconciliation calculations, including expenditures for each ACO's assigned beneficiaries for PY 2023, the national-regional blended update factor used to update the benchmark for all ACOs (refer to § 425.601(b)), and factors based on ACO participant revenue to determine the loss recoupment limits for ACOs participating under two-sided models of the BASIC track (Levels C, D, E) (refer to § 425.605(d)).

- Historical benchmark calculations for establishing the benchmark for ACOs beginning new agreement periods on January 1, 2024, January 1, 2025, or January 1, 2026, for which CY 2023 serves as benchmark year (BY) 3, BY2 and BY1, respectively (refer to § 425.652(a)).

- Factors used in the application cycle for ACOs applying to enter a new agreement period beginning on January 1, 2025, and the change request cycle for ACOs continuing their participation in the program for PY 2025, including data used to determine an ACO's eligibility for Advance Investment Payments under § 425.630(b), or for the CMS Innovation Center's new

ACO Primary Care Flex Model (ACO PC Flex Model) for the January 1, 2025, start date based on ACO revenue status (high revenue or low revenue), and to determine repayment mechanism amounts for ACOs entering, or continuing in, two-sided models for PY 2025 (refer to § 425.204(f)).

The accuracy of the Shared Savings Program's determination of an ACO's financial performance (through a process referred to as financial reconciliation) in terms of the ACO's eligibility for and amount of a shared savings payment or liability for shared losses, depends on the accuracy of claims data. Absent CMS action, the SAHS billing activity would affect PY 2023 financial reconciliation program-wide rather than being limited to ACOs that have assigned beneficiaries directly impacted by the issue. For instance:

- An ACO with assigned beneficiaries impacted by the SAHS billing activity for intermittent urinary catheters will see an increase in performance year expenditures, reducing the ACO's shared savings or increasing the amount of shared losses owed by the ACO. The impact on the ACO's performance may be partially mitigated if the SAHS billing activity also increases the ACO's regional service area expenditures and the national expenditures used to calculate the two-way national-regional blended benchmark update factor.
- An ACO with assigned beneficiary expenditures and regional service area expenditures with little or no impact from the SAHS billing activity will receive a relatively higher benchmark update under the national-regional blended update factors used in PY 2023 reconciliation, and therefore, may appear to perform better as a result of the national impact of the intermittent urinary catheters billing increase, resulting in higher earned performance payments or lower or no losses for the ACO.

Unaddressed, the SAHS billing activity will distort the historical benchmarks for an ACO that entered an agreement period beginning on January 1, 2024, or will enter an agreement period beginning on January 1, 2025, or January 1, 2026 (for which CY 2023 will continue to be a benchmark year) and the accuracy of any future financial reconciliation performed against

those benchmarks. Similarly, inaccurate revenue and expenditure calculations based on CY 2023 data may affect an ACO's revenue status and the amount of funds an ACO in a two-sided model must secure as a repayment mechanism, one of the program's important safeguards for protecting the Medicare Trust Funds. Given the scope of the SAHS billing activity, there is a high likelihood that, absent CMS action, shared savings and losses calculations for PY 2023, and for future performance years where CY 2023 is a benchmark year, will be significantly impacted for ACOs. Under these circumstances, some ACOs are likely to experience adverse impacts (for example, lower or no shared savings or higher shared losses) while other ACOs will experience windfall gains (for example, higher shared savings or lower or no shared losses).

Failing to address SAHS billing activity that occurred in CY 2023 would jeopardize the integrity of the Shared Savings Program. There are 480 ACOs in the Shared Savings Program with over 608,000 health care providers who care for 10.8 million assigned FFS beneficiaries.[1] In PY 2022, the most recent year for which data is available, savings achieved by ACOs relative to benchmarks amounted to $4.3 billion, of which ACOs received shared savings payments totaling $2.5 billion, and Medicare retained $1.8 billion in savings.[2] ACOs are held accountable for 100 percent of total Medicare Parts A and B expenditures for their assigned beneficiary populations (with limited exceptions). This incentivizes ACOs to generate savings for the Medicare program as they have the opportunity to share in those savings if certain requirements are met. It also discourages the ACO from generating unnecessary expenditures for Medicare as they may be required to repay those amounts to CMS. Accountable care arrangements such as this cannot function if the ACO may be held responsible for all SAHS billing activity that is outside of their control. Holding an ACO accountable for substantial losses due to SAHS billing activity, such as that observed in connection with the increase in billing for intermittent urinary

[1] Refer to CMS, Shared Savings Program Fast Facts—As of January 1, 2024, available at *https://www.cms.gov/files/document/2024-shared-savings-program-fast-facts.pdf*.
[2] Refer to CMS, Shared Savings Program Performance Year Financial and Quality Results, 2022, available at *https://data.cms.gov/medicare-shared-savings-program/performance-year-financial-and-quality-results/data*.

catheters, is not only inequitable but will dramatically increase the level of risk associated with participation, making the Shared Savings Program unattractive.

For these reasons, it is thus timely and appropriate to undertake notice and comment rulemaking to propose an approach for mitigating the impact of SAHS billing activity in CY 2023 on Shared Savings Program financial calculations.

II. Provisions of the Proposed Regulations

A. Identifying Codes Displaying Significant, Anomalous, and Highly Suspect Billing Activity in CY 2023

DMEPOS billing to Medicare for selected intermittent urinary catheter supplies has increased significantly since the first quarter of CY 2023, with a relatively small number of suppliers submitting a large majority of all claims for these devices. At a program level, spending in these codes remained less than 0.1 percent of total FFS spending in every year from CY 2016 to CY 2022 before increasing to nearly 1 percent in CY 2023. The SAHS billing activity has had a national impact, as evidenced by discussion of the issue in the 2024 Medicare Trustees Report, which noted a significant increase in suspected fraudulent spending on certain intermittent catheters in 2023. The DME projections in the report include the assumption that this suspected fraud will be addressed during 2024.[3]

Based on our evaluation of billing trends for individual catheter codes across CY 2023 and in consultation with the CMS Center for Program Integrity (CPI) and the CMS Office of the Actuary (OACT), we have determined that two specific HCPCS codes displayed SAHS billing activity in CY 2023: A4352 (*Intermittent urinary catheter; Coude (curved) tip, with or without coating (Teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each*) and A4353 (*Intermittent urinary catheter, with insertion supplies*). Both HCPCS codes were billed at significantly higher rates in CY 2023 compared to CY 2022 (claims increasing by 163 percent

[3] The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, "2024 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds", available at *https://www.cms.gov/oact/tr/2024*.

for A4352 and by over 5,000 percent for A4353), for which CMS was unable to identify a clear justification for the increases (for example, neither represent a newly adopted code for which a natural increase in billing might be expected). The change in claim volume is significant and unexplained, and if not addressed, would cause inaccurate and inequitable payments and repayment obligations in the Shared Savings Program. Furthermore, the growth in claims is not attributable to Medicare providers or suppliers participating in Shared Savings Program ACOs and thus outside of the ACOs' ability to reasonably control.

B. Removing Payment Amounts for Codes Displaying Significant, Anomalous, and Highly Suspect Billing Activity in Calendar Year 2023 From Shared Savings Program Expenditure and Revenue Calculations

Given our concerns about leaving SAHS billing activity unaddressed and the limitations with using an approach available under the current regulations (as we described elsewhere in this proposed rule), we propose to revise the policies governing Shared Savings Program financial calculations to mitigate the impact of SAHS billing activity for selected catheter codes identified for CY 2023. The proposals would rely on our authority under section 1899(d)(1)(B)(ii) of the Act to adjust benchmark expenditures for beneficiary characteristics and such other factors as the Secretary determines appropriate. Here, we are proposing to adjust the benchmark to remove payments for the specified catheter codes from the determination of benchmark expenditures. We propose to use our authority under section 1899(i)(3) of the Act to apply this adjustment to certain other program calculations, including the determination of performance year expenditures.

We propose to exclude all Medicare Parts A and B payment amounts for the selected catheter HCPCS codes on DMEPOS claims from expenditure and revenue calculations for CY 2023. We would perform these adjustments for calculations for CY 2023 when it is the performance year, including when CY 2023 is used to calculate the ACO's performance year expenditures and when it is used to calculate the national-regional blended update to the

benchmark used in determining financial performance for PY 2023, and also when CY 2023 is a benchmark year for ACOs in agreement periods beginning on January 1, 2024, January 1, 2025, or January 1, 2026. In performing this adjustment, we would remove payment amounts for the selected catheter HCPCS codes on DMEPOS claims submitted by any supplier; that is, we would not limit the exclusion to payment amounts on claims submitted by certain suppliers that may have individually displayed SAHS billing activity so as to protect the integrity of any potential investigations which may be ongoing.

Specifically, we would adjust the following Shared Savings Program calculations, as applicable, to exclude all Medicare Parts A and B payment amounts on DMEPOS claims (claim types 72 and 82)[4] associated with HCPCS codes A4352 and A4353 in CY 2023:

- Calculation of Medicare Parts A and B FFS expenditures for an ACO's assigned beneficiaries for all purposes including the following: Establishing, adjusting, updating, and resetting the ACO's historical benchmark and determining performance year expenditures.

- Calculation of FFS expenditures for assignable beneficiaries as used in determining county-level FFS expenditures and national Medicare FFS expenditures, including the following calculations:

++ Determining average county FFS expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area according to §§ 425.601(c) and 425.654(a) for purposes of calculating the ACO's regional FFS expenditures.

++ Determining the 99th percentile of national Medicare FFS expenditures for

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[4] We note that in some Shared Savings Program documentation (see, for example, Table 2 in the Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version #11, January 2023), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2*), we classify claim type 72 (along with claim type 71) as Carrier (including physician/supplier Part B) and we classify claim type 82 (along with claim type 81) as DME. We will continue to use these classifications, which are based on the type of carrier to which the claim was submitted, for other program operations. As described by the CMS Research Data Assistance Center (ResDAC), claim type 71 refers to local carrier non-DMEPOS claims, 72 to local carrier DMEPOS claims, 81 to durable medical equipment regional carrier (DMERC) non-DMEPOS claims, and 82 to DMERC DMEPOS claims (see https://resdac.org/cms-data/variables/nch-claim-type-code).

assignable beneficiaries for purposes of the following:

-- Truncating assigned beneficiary expenditures used in calculating benchmark expenditures under § 425.652(a)(4), and performance year expenditures under §§ 425.605(a)(3) and 425.610(a)(4).

-- Truncating expenditures for assignable beneficiaries in each county for purposes of determining county FFS expenditures according to §§ 425.601(c)(3) and 425.654(a)(3).

-- Truncating expenditures for assignable beneficiaries for purposes of determining truncated national per capita FFS expenditures for purposes of calculating the Accountable Care Prospective Trend (ACPT) according to § 425.660(b)(3).

++ Determining truncated national per capita expenditures FFS per capita expenditures for assignable beneficiaries for purposes of calculating the ACPT according to § 425.660(b)(3).

++ Determining national per capita expenditures for Parts A and B services under the original Medicare FFS program for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark according to § 425.656(c)(3), and capping the prior savings adjustment according to § 425.658(c)(1)(ii).

++ Determining national growth rates that are used as part of the blended growth rates used to trend forward benchmark year (BY) 1 and BY2 expenditures to BY3 according to § 425.652(a)(5)(ii) and as part of the blended growth rates used to update the benchmark according to §§ 425.601(b)(2) and 425.652(b)(2)(i).

- 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 as specified in § 425.605(d).

- 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, as defined under § 425.20, and determining an ACO's eligibility to receive advance investment payments

according to § 425.630.

- Calculation or recalculation of the amount of the ACO's repayment mechanism arrangement according to § 425.204(f)(4).

This approach would recognize that SAHS billing activity has the potential to impact an ACO's savings and loss determination for both PY 2023 (the year when the SAHS billing activity occurred) and future performance years for which CY 2023 is a benchmark year. Making adjustments when the affected period represents a performance year or benchmark year is consistent with our approach for the exclusion of payment amounts for episodes of care for treatment of COVID-19 that we established in the May 8, 2020 COVID-19 IFC (85 FR 27577 through 27581).

The listed calculations reflect the same set of calculations that CMS adjusts for a beneficiary's episode of care for treatment of COVID-19, specified at § 425.611(c), as amended by the CY 2021 PFS final rule (85 FR 85044), the CY 2023 PFS final rule (87 FR 70241), and the CY 2024 PFS final rule (88 FR 79548), with a few exceptions. First, § 425.611(c) includes certain provisions that are not relevant for the proposed policy.[5] Second, the proposed policy includes calculations related to truncated national per capita expenditures used in determining the ACPT as described in § 425.660(b)(3) that are not included in § 425.611(c).[6]

For agreement periods beginning on January 1, 2024, and in subsequent years, CMS incorporates a fixed projected growth rate determined at the beginning of the ACO's agreement

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[5] This includes provisions under §§ 425.600, 425.602, 425.603, 425.604, and 425.606 which are not relevant for the proposed policy because they are not applicable to PY 2023 or for agreement periods where CY 2023 is a benchmark year. It also includes certain provisions under § 425.601 which are not relevant for the proposed policy because the proposed policy does not include adjustments to benchmark year calculations for the benchmarks used to financially reconcile ACOs for PY 2023. These provisions are relevant for the COVID-19 episode exclusion policy under § 425.611 because they are applicable to performance or benchmark years that overlap with the PHE for COVID-19.

[6] When establishing the ACPT in the CY 2023 PFS final rule, we noted that the first ACPT release would be published in 2024 for agreement periods beginning on January 1, 2024, and would provide a projected annualized growth rate (or rates) relative to the 2023 benchmark year (BY3). We noted further that to the extent that Medicare projections made at that time (2024) anticipated lingering effects from the COVID-19 pandemic then they would be reflected in the ACPT (see 87 FR 69894), and we opted not to amend § 425.611 to include adjustments of ACPT-related calculations. However, given the known nation-wide impact of the SAHS billing activity in CY 2023, it is appropriate to propose making adjustments to ACPT-related calculations in this proposed rule.

period called the ACPT into the blended update factor described in § 425.652(b) when updating an ACO's benchmark for each performance year of the agreement period.[7] Specifically, the ACPT is an annual rate of growth in projected expenditures during the ACO's 5-year agreement period relative to BY3 and is calculated using a modified version of the existing FFS United States Per Capita Cost (USPCC) growth trend projections. The USPCCs are calculated by OACT and projects Medicare program spending for various recurring deliverables, including the Medicare Trustees Report and the Advance Notice and Announcement of Medicare Advantage capitation rates and Part C and Part D payment policies. These publications include both historical and projected future Medicare spending amounts expressed on a per capita basis. The Modified USPCC Annualized Growth Rate used for calculating the ACPT in the Shared Savings Program reflects the following: (1) exclusion of IME and DSH payments, and the supplemental payment for Indian Health Service/Tribal hospitals and Puerto Rico hospitals; and (2) inclusion of payments associated with hospice claims (see § 425.660(b)(1), see also 87 FR 69882).

In considering whether to propose adjusting calculations used for the ACPT, we considered whether adjusting Shared Savings Program calculations detailed earlier in this section to exclude all payment amounts for the selected catheter codes but not adjusting projected growth rates used in the three-way blend would result in a bias. We expect that a bias would be introduced if we adjusted Shared Savings Program calculations to remove SAHS billing activity from expenditures but did not make an adjustment for SAHS billing activity from the corresponding year used in ACPT projections. We thus determined it was necessary to adjust the ACPT to promote continued integrity and fairness and improve the accuracy of Shared Savings Program financial calculations. This would ensure that the projected growth rates in future years (for which billing for the selected catheter claims is expected to revert to typical levels) would

[7] For more details on the ACPT and the terminology used to describe it, refer to the CY 2023 PFS final rule (87 FR 69881 through 69898) and Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology, Specifications of the Accountable Care Prospective Trend (ACPT) and Three-Way Blended Benchmark Update Factor (May 2023, Version #1), available at *https://www.cms.gov/files/document/medicare-ssp-acpt-specifications.pdf.*

not be biased.

As noted in the Regulatory Impact Statement (section VI. of this proposed rule), we anticipate that the magnitude and direction of the net impact of these various adjustments may vary from ACO to ACO. For example, excluding the selected catheter payments may reduce an ACO's performance year expenditures, but may also reduce the performance year regional and national expenditures and, in turn, the update factors applied to the ACO's historical benchmark. If the reduction to an ACO's expenditures is larger than the reduction to the national-regional blended update to the benchmark (indicating that the ACO's performance year assigned population was disproportionately impacted by the SAHS billing activity than assignable beneficiaries in the ACO's regional service area or the nation as a whole), the ACO would see an increase in total savings (or a reduction in total losses) relative to the current methodology, which makes no adjustments for SAHS billing activity. Conversely, if the reduction to the ACO's performance year expenditures is smaller than the reduction to the national-regional blended update to the benchmark, the ACO would see a decrease in total savings (or increase in total losses) relative to the current methodology.

We acknowledge that by excluding all payments for the selected HCPCS codes from CY 2023 calculations, we would exclude some payments that would have been made during the period in the absence of any SAHS billing activity. This, in turn, would create some degree of inconsistency between performance year expenditure calculations and expenditure calculations for the historical benchmark against which the performance year will be reconciled, as years not directly affected by the SAHS billing activity include some level of payments for the selected codes. We considered whether to propose adjusting historical benchmarks that will be used for PY 2023 financial reconciliation to remove all payments for the selected codes from benchmark year expenditures (for example, for an ACO that started an agreement period in 2022, adjusting the benchmark used for PY 2023 financial reconciliation to remove payments for the selected codes from benchmark years 2019, 2020, and 2021). We opted against this approach for two

reasons.

First, historical billing for the selected catheter HCPCS codes has generally been relatively low, including in recent years. As noted in the Regulatory Impact Statement (section VI. of this proposed rule), billing for these codes remained less than 0.1 percent of total FFS billing in every year from 2016 to 2022, the period encompassing all benchmark years for ACOs being financially reconciled for PY 2023. Thus, in a year not impacted by SAHS billing activity, payments for these codes would likely represent only a very small portion of an ACO's total per capita expenditures or total expenditures for an ACO's regional service area or the national assignable population. This conclusion is supported by analysis at the regional level. Tabulating the difference in per capita spending for these codes at the Hospital Referral Region (HRR) from national average per capita spending across 2016 to 2022 (and expressing such difference as a percentage of per capita spending) results in a standard deviation of only 0.03 percentage points. Therefore, we believe that the impact of adjusting the benchmarks to be used for PY 2023 financial reconciliation to exclude the selected catheter payments would be very small.

Second, adjusting benchmarks for over 450 ACOs being reconciled for PY 2023 would require the recalculation of ACO, national, and regional expenditures for seven benchmark calendar years and recalculation of benchmarks under multiple benchmarking methodologies. Performing these adjustments would delay the issuance of initial determinations, and thus the disbursement of earned performance payments, potentially by several months. The SAHS billing activity in CY 2023 was unforeseen and could not have been planned for or integrated into existing operational timelines. It would take time to recompute expenditure calculations for multiple years and benchmark calculations for multiple cohorts of ACOs and review and validate the results. Such a delay would be harmful to ACOs and the beneficiaries they care for, as ACOs rely on earned performance payments for critical investments in care delivery. The negative implications of a delay to the issuance of initial determinations and earned performance payments for PY 2023 outweighs the potential benefits gained by adjusting the benchmarks,

especially as we anticipate the magnitude of the impact of such adjustments would be small.

Section 1899(d)(1)(B)(ii) of the Act permits the Secretary to adjust the benchmark for beneficiary characteristics and such other factors as the Secretary determines appropriate. This proposal, if finalized, would rely on this authority to remove payments for the specified catheter codes from the determination of benchmark expenditures where CY 2023 serves as a benchmark year when establishing benchmarks for ACOs in agreement periods beginning in January 2024, 2025, or 2026.

Other changes are proposed using our authority under section 1899(i)(3) of the Act. Specifically, we would rely on section 1899(i)(3) of the Act to remove payment amounts for HCPCS or CPT codes for which CMS has identified SAHS billing activity from the following calculations: (1) performance year expenditures; (2) updates to the historical benchmark; and (3) ACO participants' Medicare FFS revenue used for multiple purposes across the Shared Savings Program, including determinations of loss sharing limits in the two-sided models of the BASIC track[8] and determinations of eligibility for advance investment payments.[9] Section 1899(i)(3) of the Act requires that we determine that the alternative payment methodology adopted under that provision would improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures. The adjustments we are proposing herein, which would remove payment amounts for codes with identified SAHS billing activity from the specified Shared Savings Program calculations specified in a proposed new section of the regulations at § 425.670, would capture and remove from program calculations expenditures that are outside of an ACO's control, but that could significantly affect the ACO's performance under the program. In particular, failing to remove these payments would create highly variable savings and loss results for individual ACOs that happen to have over-representation or under-representation of SAHS billing activity for the selected codes among

[8] See § 425.605(d)(1)(iii)(D), 425.605(d)(1)(iv)(D), and 425.605(d)(1)(v)(D) for BASIC track Levels C, D and E, respectively.
[9] See § 425.630(b).

their assigned beneficiary populations.

As described in the Regulatory Impact Statement (section VI. of this proposed rule), excluding payment amounts for the selected catheter HCPCS codes from the specified calculations is not expected to result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) of the Act. Further, these adjustments to our calculations to remove payment amounts for these codes would promote continued integrity and fairness and improve the accuracy of Shared Savings Program financial calculations as well as timely completion of PY 2023 financial reconciliation. As a result, we expect these policies would support ACOs continued participation in the Shared Savings Program and the program's goals of lowering growth in Medicare FFS expenditures and improving the quality of care furnished to Medicare beneficiaries.

Based on these considerations, and as specified in the Regulatory Impact Statement (section VI. of this proposed rule), we have determined that adjusting certain Shared Savings Program calculations to remove payment amounts for selected codes identified as having SAHS billing activity in CY 2023 from the calculation of performance year expenditures, updates to the historical benchmark, and ACO participants' Medicare FFS revenue used for multiple purposes across the Shared Savings Program, meets the requirements for use of our authority under section 1899(i)(3) of the Act when incorporated into the existing other payment model we have established pursuant to that section.

The proposals described in this proposed rule would be applied retroactively, as they affect a performance year that has already been completed (PY 2023) and a performance year that has already started (PY 2024). More specifically, we would retroactively apply the changes (if finalized) to adjust expenditure calculations used in determining shared savings and losses for PY 2023 and certain other calculations including to establish historical benchmarks for ACOs entering an agreement period beginning on January 1, 2024, that would be used to determine ACO financial performance for PY 2024 and subsequent years of an ACO's agreement period.

Therefore, if finalized, these changes would constitute retroactive rulemaking. Section 1871(e)(1)(A)(ii) of the Act permits a substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under Title XVIII of the Act to be applied retroactively to items and services furnished before the effective date of the change if the failure to apply the change retroactively would be contrary to the public interest.

Failing to apply the proposed changes retroactively would be contrary to the public interest because it would unfairly punish Shared Savings Program ACOs by forcing them to unexpectedly assume a substantial magnitude of unexpected financial risk for costs outside their control and not previously contemplated in the Shared Savings Program, undermining both the sustainability of the Shared Savings Program and the public's faith in CMS as a fair partner. We did not fully contemplate the potential for SAHS billing activity outside of an ACO's control when the Shared Savings Program was established.[10] For this reason, the Shared Savings Program financial methodology and the procedures we have utilized in the past did not provide a means to adequately account for instances of SAHS billing activity outside of an ACO's control, and thereby the related financial risk is assumed entirely by ACOs. We view this outcome as particularly inequitable to ACOs because they have no direct means of controlling such costs. Unlike Medicare Advantage organizations, ACOs are not responsible for processing claims for their assigned beneficiaries and otherwise have no means of causing the denial of such claims. CMS thus cannot reasonably have expected ACOs to have assumed responsibility for all instances of SAHS billing activity outside of an ACO's control when they joined the Shared Savings Program. For these reasons, it would be contrary to the public interest for CMS to fail to apply a policy mitigating this issue retroactively.

Undertaking notice and comment rulemaking for this issue prior to the start of PY 2023

[10] *See, for example*, 76 FR 67948 through 67950. Such approaches were more focused on policies to support monitoring of ACO performance and ensuring program integrity.

to avoid retroactive rulemaking was not possible because we could not have foreseen the SAHS billing activity prior to the start of the performance year. More specifically, we were only able to determine that the increase in billing on HCPCS codes A4352 and A4353 in CY 2023 was significant, anomalous, and highly suspect after the calendar year ended. To identify that the billing activity in CY 2023 was significant, anomalous, and highly suspect, CMS reviewed actual billing levels after the calendar year closed and services furnished in CY 2023 had occurred and the billing level could then be compared to billing levels observed in prior calendar years.

We are proposing adding and reserving §§ 425.661 through 425.669 in subpart G and adding a new section at § 425.670 to describe adjustments CMS would make to Shared Savings Program calculations to mitigate the impact of SAHS billing activity occurring in CY 2023. We propose that § 425.670(b) would specify that CMS has determined that the billing of HCPCS codes A4352 (*Intermittent urinary catheter; Coude (curved) tip, with or without coating (Teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each*) and A4353 (*Intermittent urinary catheter, with insertion supplies*) represents significant, anomalous, and highly suspect billing activity for CY 2023 that warrants adjustment. We propose under § 425.670(c) to specify the Shared Savings Program calculations for which CMS would exclude all Medicare Parts A and B FFS payment amounts on DMEPOS claims (claim types 72 and 82) associated with HCPCS codes A4352 and A4353 and include references to all relevant sections of the regulations in these provisions. In § 425.670(d), on the period of adjustment, we propose to specify that CMS would adjust Shared Savings Program calculations for SAHS billing activity of HCPCS codes A4352 and A4353 for CY 2023, when CY 2023 is either a performance year or a benchmark year. We propose to specify under § 425.670(e) that we would make adjustments for payments associated with HCPCS codes A4352 and A4353 for BY3 in projecting per capita growth in Parts A and B FFS expenditures, according to § 425.660(b)(1), for purposes of calculating the ACPT for agreement periods beginning on January 1, 2024.

We seek comment on these proposals.

III. Exception to the 60-day Comment Period and Possible Reduction or Waiver of 30-day Delay in Effective Date of a Final Rule

A. Reduction of the Comment Period to 30 Days

There is an urgent need to address the impact of SAHS billing activity on Shared Savings Program calculations based on CY 2023 data used in determining PY 2023 financial performance, in establishing benchmarks for ACOs participating in agreement periods beginning on January 1, 2024, and in calculating factors used in the application cycle for ACOs applying to enter a new agreement period beginning on January 1, 2025, and the change request cycle for ACOs continuing their participation in the program for PY 2025.[11] These program operations depend on the timely use of CY 2023 data. Notice and comment rulemaking to consider the proposed adjustments to Shared Savings Program calculations for SAHS billing activity identified for CY 2023 necessitates delaying key program operations that depend on CY 2023 data, pending the issuance of a final rule that would specify our final policy as informed by public comment on our proposals. We describe in this section of this proposed rule the impact of delayed use of CY 2023 data in the aforementioned program operations and approaches that would allow us to continue to meet the statutory requirements for notice and comment rulemaking procedures, such as by reducing the comment period, and possibly reducing or eliminating the delay in the effective date of a final rule (if issued).

Significant delays in the issuance of initial determinations for PY 2023 financial performance, and related shared savings payments, would be substantially disruptive to ACOs that exclusively receive revenue from shared savings payments, particularly small, rural, and low revenue ACOs and those serving underserved populations. With few exceptions, the Shared Savings Program historically completes calculations of shared savings and shared losses and issues initial determinations of ACO financial performance approximately 8 months after the

[11] Failing to take any action to address this SAHS billing activity may require CMS to use inaccurate data to make eligibility determinations and require ACOs establish repayment mechanism arrangements for inflated amounts that include the impact of SAHS billing activity.

conclusion of the performance year, and shortly thereafter issues performance payments to ACOs eligible to share in savings.[12] CMS initiates payments to ACOs that have earned shared savings for a performance year in September of the year following the applicable performance year. ACOs have come to rely on the orderly and timely calculation of financial reconciliation, and distribution of shared savings. Modifications to Shared Savings Program financial methodology as proposed in this proposed rule would necessitate delaying the delivery of financial reconciliation reports to ACOs, and issuance of performance payments to ACOs that have earned shared savings.

Delayed use of CY 2023 data would also impair administration of the Shared Savings Program in 2024 and 2025. CY 2023 data is instrumental in determining factors used in the application cycle for ACOs applying to enter a new agreement period beginning on January 1, 2025, and change request cycle for existing ACOs continuing their participation in the program for PY 2025. For instance, CY 2023 data will be used in the 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 high revenue or low revenue, as defined under § 425.20. The high/low revenue status is then used to determine an ACO's eligibility to receive advance investment payments to expand accountable care to underserved communities according to § 425.630, and an ACO's eligibility for the CMS Innovation Center's new ACO PC Flex Model for the January 1, 2025 start date. CY 2023 data will also be the basis for calculating the amount of required repayment mechanism arrangements for ACOs entering two-sided models for PY 2025. The proposed approach would help ensure the accuracy of the calculations used in determining ACO revenue status and repayment mechanism amounts. Delays in the application cycle already underway could jeopardize our ability to timely issue application dispositions, execute participation agreements with eligible ACOs for the new agreement period beginning on January 1, 2025, deliver PY 2025 initial assignment list reports,

[12] Refer to discussion in the CY 2023 PFS final rule, 87 FR 69869 through 69870.

and timely deliver initial advance investment payments for newly eligible ACOs. Substantial delays in change request cycle milestones also would jeopardize our ability to ensure ACOs have met program requirements to facilitate their continued participation in the Shared Savings Program for the performance year beginning on January 1, 2025.

Modifications to Shared Savings Program financial methodology as proposed in this proposed rule also necessitate delaying the delivery of final historical benchmark reports to ACOs. We recognize that delaying the availability of these program reports to ACOs could hamper ACOs' ability to set effective cost targets that may depend on the ACO's projected financial performance based on its benchmark value. Substantial delays in issuance of the historical benchmark reports to ACOs could make it more challenging for ACOs to effectively curb growth in Medicare FFS expenditures, a central aim of the Shared Savings Program.

Section 1871(b)(1) of the Act generally requires that Medicare rules must be proposed with a 60-day comment period. Section 1871(b)(2) of the Act provides that this requirement does not apply where a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment; a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained; or subsection (b) of section 553 of title 5, United States Code, does not apply under subparagraph (B) of such subsection. Subparagraph (B) of 5 U.S.C. 553(b) provides an exception to the requirement for an agency to publish a general notice of proposed rulemaking in the **Federal Register** when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

We find that a 60-day comment period is both impracticable and contrary to the public interest. For the reasons stated in the following discussion, we are therefore reducing the comment period of this proposed rule to 30 days. Failing to use a 30-day comment period in lieu

of a 60-day comment period here would be impracticable and contrary to the public interest in part for the same reasons described in section II.B. of this proposed rule that failing to apply this rule retroactively to PY 2023 and PY 2024 would be contrary to the public interest. Additionally, failing to use the reduced comment period would be impracticable and contrary to the public interest because the additional time would not substantially enhance the public's ability to participate in this rulemaking, and it would substantially impair CMS's ability to administer the Shared Savings Program, by delaying the following:

- Issuance of initial determinations of shared savings and shared losses to ACOs for PY 2023.
- Disbursement of PY 2023 earned performance payments to ACOs.
- Determination of ACO revenue status used in determining ACO eligibility for advance investment payments and eligibility for the ACO PC Flex Model, in connection with the application cycle for ACOs applying to enter a new agreement period beginning on January 1, 2025.
- Calculation of required amounts for repayment mechanism arrangements for ACOs entering a two-sided model for PY 2025 and the deadline for ACO submission of repayment mechanism documentation to CMS for review, to ensure compliance with related requirements.
- Calculation of final historical benchmarks for ACOs beginning an agreement period on January 1, 2024, and delivery of final historical benchmark reports to ACOs.

It would be contrary to the public interest for ACOs to be harmed by the delay in administration of the Shared Savings Program caused by the rule that intended to relieve them from the unexpected harm arising from SAHS billing activity. A 60-day comment period would likely necessitate delaying these key operations until at least late 2024, substantially delaying these operations and related processes, which would harm ACOs and impair the operation of the Shared Savings Program and thwart the relief to ACOs that would otherwise be provided by this rule.

A substantial delay to initial determinations of shared savings and losses for PY 2023 and disbursement of earned performance payments would be financially ruinous to the many ACOs that rely on these payments to operate. For example, in PY 2022, 304 ACOs earned $2.52 billion in performance payments. Shared savings payments are the primary revenue source of ACOs. Many ACOs, particularly small, rural, and low revenue ACOs and those serving underserved populations, depend on receiving shared savings payments on a predictable annual schedule to continue operating. It is self-evident that enabling ACOs to continue to operate with minimal disruption is itself in the public interest and in particular is in the interest of Medicare beneficiaries whose care is coordinated by ACOs.

Delaying adjudication of application and repayment mechanism decisions also would jeopardize or prevent CMS and ACOs starting performance year 2025. CMS and ACOs cannot timely enter into agreements for the agreement period beginning on January 1, 2025, jeopardizing the expansion of accountable care to underserved communities, stifling innovation in primary care payment reform and restricting ACOs' ability to meet requirements for entering or continuing their participation in a two-sided model for PY 2025. Phase 1 of the application period closed June 17, 2024.[13] Failing to timely adjudicate hundreds of applications and over ten thousand change requests, for new and renewing ACOs, and ACOs continuing their participation in Shared Savings Program, impairs our ability to timely and accurately evaluate ACOs based on statutorily required eligibility criteria and existing regulatory requirements. We cannot start performance year 2025 until all applications and change requests have been reviewed, processed, and adjudicated.

Additionally, given the limited scope of this proposed rule, addressing a single issue through proposed changes to the Shared Savings Program regulations, a 30-day comment period is a reasonable amount of time for public inspection and comment. Furthermore, many interested

[13] See for example, Medicare Shared Savings Program, Key Application Actions and Deadlines For Agreement Period Beginning on January 1, 2025, available at *https://www.cms.gov/files/document/key-application-actions-and-deadlines.pdf*.

parties have written to the Administrator requesting relief from SAHS billing activity so they are familiar with this issue and are likely ready to review the policy and impacts within the thirty day timeframe.

Furthermore, starting notice and comment rulemaking sooner to allow a 60-day comment period was impracticable. As we described elsewhere in this proposed rule, we could not have foreseen the SAHS billing activity in advance and were only able to determine that the increase in billing on HCPCS codes A4352 and A4353 in CY 2023 was significant, anomalous, and highly suspect after the calendar year ended. To identify that the billing activity in CY 2023 was SAHS billing activity, CMS reviewed actual billing levels after the calendar year closed and services furnished in CY 2023 had occurred and the billing level could then be compared to billing levels observed in prior calendar years. Careful analysis of the billing activity, plus careful analysis of the impact on ACOs in the Shared Savings Program, was critical to determining whether mitigation measures were necessary. Given the unprecedented nature of the circumstances, time was also required to develop the appropriate proposed mitigation approach. Once we determined that this billing activity in CY 2023 was significant, anomalous, and highly suspect, that it was necessary to mitigate its impact on Shared Savings Program expenditures and revenue calculations, and the appropriate proposed mitigation approach, we immediately began the process to undertake notice and comment rulemaking. For the aforementioned reasons, among others discussed in this section of this proposed rule, we view a failure to use a reduced comment period as impracticable and contrary to the public interest, and thus find the agency has good cause to set a 30-day comment period.

The modifications to the Shared Savings Program financial methodology proposed in this proposed rule, with a 30-day comment period, would allow us to maintain timely adjudication of certain determinations of applicant ACOs' eligibility to participate under the advance investment payment option, or the ACO PC Flex Model, for an agreement period beginning on January 1, 2025, and timely finalization of repayment mechanism arrangements required for ACOs to enter

or continue their participation in two-sided models for PY 2025. While using a 30-day comment period would minimize disruptions to timelines for certain milestones, we anticipate that the issuance of initial determinations and the disbursement of earned performance payments for PY 2023 would still be delayed by approximately 6 weeks. Where possible, we will work to reduce delays and will proactively communicate with ACOs about changes in timelines for these, or other, milestones.

B. Possible Waiver of the 30-day Delay in Effective Date of a Final Rule

Section 1871(e)(1)(B)(i) of the Act prohibits a substantive change in Medicare regulations from taking effect before the end of the 30-day period beginning on the date the rule is issued or published. However, section 1871(e)(1)(B)(ii) of the Act permits a substantive rule to take effect on a date that precedes the end of the 30-day period if the Secretary finds that a waiver of the 30-day period is necessary to comply with statutory requirements or that the application of the 30-day period is contrary to the public interest. The Administrative Procedure Act (APA), 5 U.S.C. 553(d), similarly requires a 30-day delay in the effective date of a substantive final rule. This 30-day delay in effective date can be waived, however, if an agency finds good cause to support an earlier effective date, among other reasons. 5 U.S.C. 553(d)(3). Should CMS finalize a rule based on this proposed rule, we would strongly consider reducing or waiving the 30-day delay in effective date under the provisions described above to the extent that the delay in effective date would also harm ACOs or thwart the purpose of this proposal by delaying our timely administration of the Shared Savings Program functions described in section III.A of this proposed rule. This waiver would be in part for the same reasons that we are reducing the comment period on this proposed rule from 60 days to 30 days, as described in section III.A of this proposed rule. We request comment on this approach, including a possible finding of good cause and how ACOs are impacted by the delay.

IV. Collection of Information Requirements

Section 1899(e) of the Act provides that chapter 35 of title 44 U.S.C., which includes

such provisions as the Paperwork Reduction Act of 1995, shall not apply to the Shared Savings Program. Accordingly, we are not setting out burden estimates under this section of the preamble. Please refer to section VI. (Regulatory Impact Statement) of this proposed rule for a discussion of the impacts associated with the proposed changes to the Shared Savings Program as described in section II. (Provisions of the Proposed Regulations) of this proposed rule.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Statement

A. Overview

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled "Modernizing Regulatory Review" (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 entitled "Modernizing Regulatory Review" (hereinafter, the Modernizing E.O.) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). A Regulatory Impact Analysis (RIA)

must be prepared for major rules with significant effects ($200 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is not significant per section 3(f)(1) as measured by the $200 million or more in any 1 year.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $9.0 million to $47.0 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2024, that threshold is approximately $183 million. This rule will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

B. Analysis

In this proposed rule, we discuss the reasons that excluding payment amounts incurred in 2023 for two urinary catheter HCPCS codes[14] on DMEPOS claims will prevent SAHS billing activity from deteriorating the accuracy of Shared Savings Program calculations determining both: (1) shared savings or losses for PY 2023 and (2) historical benchmarks for future performance years for ACOs entering agreement periods in 2024, 2025 or 2026. Total FFS spending in the two specified codes was minimal in preceding years before the SAHS billing activity in 2023 sharply increased in highly-disparate ways. At a program level, billing for these codes remained less than 0.1 percent of total FFS billing in every year from 2016 to 2022 before increasing to nearly 1 percent in 2023. And while a handful of hospital referral regions (HRRs) still managed to exhibit billing for the specified codes totaling less than 0.1 percentage points of total spending, approximately 10 percent of HRRs showed billing for the specified codes rising to at least 2 percentage points of total spending. In the most impacted HRR, billing for these codes in 2023 accounted for over a 5 percentage-point increase in total per capita billing from 2022, an astonishing and plainly unjustifiable increase in billing for the medical device supplied under these codes. By analyzing ACO-level program data, we observed material impacts likely for many PY 2023 ACOs related to these geographically heterogeneous and highly suspect increases in spending for the specified urinary catheter codes.

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

A preliminary estimate of PY 2023 performance using fourth-quarter reports with limited claims runout was used to estimate the impact of removing the specified codes. Despite limitations inherent in this analysis (including reliance on non-final beneficiary assignment lists, the absence of 3-months of claims run out, and the exclusion of risk adjustment), simulating the removal of actual observed spending for the specified codes from preliminary estimates for ACO-level spending and regional and national growth and resulting updated benchmark spending provides a meaningful approximation of the distribution of impacts that the policy would have across the mix of ACOs in the program in 2023.

Billing for the specified codes was estimated in this study to have a nominal impact to overall shared savings (net of losses) across the mix of ACOs in PY 2023. The neutral overall impact exemplifies to the fact that billing for these specific codes was not correlated to any ability for an average ACO to actively manage the rapid growth. For most ACOs, the inclusion of the specified catheter codes do not substantially change their estimated financial outcome in PY 2023. When expressing projected shared savings (or losses) as a percentage of benchmark, the impact of spending in the specified codes on projected shared savings (or losses) was projected to be within +/-0.05 percent for 49 percent of ACOs, within +/-0.10 percent for 72 percent of ACOs, and within 0.15 percent for 82 percent of ACOs. However, the impacts will potentially be substantial at the tails of the distribution. Table 1 shows that including the specified codes would have increased the net earnings for one ACO in the study by an amount equivalent to 1.5 percent of benchmark spending relative to the proposal to exclude such specified spending. At the other extreme, leaving in the specified codes was estimated to reduce earnings to another ACO by an amount equivalent to 2.8 percent of benchmark relative to the proposed method to exclude such specified codes. The impact estimated at these extremes highlights the benefit of the proposed policy to prevent highly suspect billing in the two specified codes from materially impacting outcomes in the program.

TABLE 1: Distribution of Estimated Impacts Elevated Catheter Spending (HCPCS codes

A4352 and A4353) Would Have Imparted on Individual ACOs in PY 2023 Absent the Proposal (ACO Impacts Expressed as Percent of Estimated Updated PY 2023 Benchmark Excluding Specified Catheter Codes)

		Change in ACO Gross Savings	Change in ACO Earnings (Shared Savings /Losses)
	Mean	**-0.1%**	**0.0%**
	Min	-7.3%	-2.8%
Percentiles	5th	-0.7%	-0.4%
	10th	-0.3%	-0.1%
	20th	-0.1%	-0.1%
	30th	0.0%	0.0%
	40th	0.0%	0.0%
	50th	0.1%	0.0%
	60th	0.1%	0.0%
	70th	0.1%	0.0%
	80th	0.2%	0.1%
	90th	0.3%	0.1%
	95th	0.4%	0.2%
	Max	1.0%	1.5%

While still providing a valid illustration of the impacts likely across the distribution of ACOs, the simulation relied on preliminary data for PY 2023 with less than seven days of claims runout and without risk adjustment. Because of the limitations in the data used for this simulation, and because of the potential for the overall impact to be influenced by the proximity of individual ACO-level outcomes to the applicable minimum savings rate or minimum loss rate (particularly for large ACOs), a stochastic simulation was employed to generate a range of outcomes surrounding the best estimate. Assuming final gross savings (expressed on percent of benchmark basis) would vary relative to data used in the analysis under a normal distribution with standard deviation of 0.3 percentage points, the impact of removing spending in the specified codes was estimated to reduce overall program shared savings outlays by $10 million on average, ranging from a $40 million decrease at the 10th percentile to a $20 million dollar increase at the 90th percentile.

C. Compliance with Requirements of Section 1899(i)(3) of the Act

Certain policies, including both existing policies and the proposed new policy described in this proposed rule, rely upon 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. By preventing SAHS spending growth in the two catheter codes from disrupting the accuracy and fairness of shared savings and loss outcomes for ACOs in the 2023 performance year, the proposed policy furthers the goals of quality and efficiency by protecting the validity and integrity of the program's incentive for quality and efficiency. The proposal in this proposed rule, together with all existing program policies (including but not limited to those requiring authority granted in section 1899(i)(3) of the Act), results in a program that is expected to improve the quality and efficiency of items and services furnished under the Medicare program and is not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act.

In the CY 2023 PFS final rule, we estimated that the projected impact of the payment methodology that incorporates all policies finalized by that final rule would result in $4.9 billion in greater program savings compared to a hypothetical baseline payment methodology that excluded the policies that required section 1899(i)(3) of the Act authority (see 87 FR 70195 and 70196). The marginal impact of the proposed changes in the CY 2024 PFS final rule were estimated to lower net spending by $330 million over the ten-year window for all new policies combined, including the cap an ACO's regional service area risk score growth, the addition of a new third step to the beneficiary assignment methodology, and the revised approach to identify the assignable beneficiary population (88 FR 79496). The marginal impact of the proposed changes in this proposed rule are estimated to lower net spending by an additional $10 million in

net program shared savings payments for the 2023 performance year, with a range of uncertainty spanning $40 million lower spending at the 10th percentile to $20 million higher spending at the 90th percentile. The cumulative impact of all policies including the proposals in this proposed rule are estimated to result in more than $4.9 billion in greater program savings compared to the hypothetical baseline payment methodology that excludes policies that require 1899(i)(3) of the Act authority. Therefore, we estimate that the implementation of the proposal made in this proposed rule would not result in a program with spending greater than what would result under the statutory payment model, consistent with the requirements of section 1899(i)(3)(B) of the Act.

We will continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. Additional Shared Savings Program data beginning to accumulate after the end of the COVID-19 public health emergency, along with emerging information on the characteristics of new entrants in the Shared Savings Program for agreement periods beginning on January 1, 2024 and January 1, 2025, are anticipated to gradually improve our ability to reevaluate program impacts in a comprehensive fashion. In the event that we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 27, 2024.

List of Subjects in 42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare,

Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 425 as set forth below:

PART 425—MEDICARE SHARED SAVINGS PROGRAM

1. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

§§ 425.661 through 425.669 [Reserved]

2. Add reserved §§ 425.661 through 425.669 to subpart G.

3. Section 425.670 is added to subpart G to read as follows:

§ 425.670 Adjustments to mitigate the impact of significant, anomalous, and highly suspect billing activity on Shared Savings Program financial calculations involving calendar year 2023.

(a) *General.* This section describes adjustments CMS makes to Shared Savings Program calculations to mitigate the impact of significant, anomalous, and highly suspect billing activity occurring in calendar year 2023.

(b) *Significant, anomalous, and highly suspect billing activity for a HCPCS or CPT code impacting Shared Savings Program calculations.* CMS has determined that the billing of the following HCPCS codes represents significant, anomalous, and highly suspect billing activity for calendar year 2023 that warrants adjustment --

(1) A4352 (*Intermittent urinary catheter; Coude (curved) tip, with or without coating (Teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each*); and

(2) A4353 (*Intermittent urinary catheter, with insertion supplies*).

(c) *Applicability of adjustments to performance year and benchmark year calculations*. Notwithstanding any other provision in this part, CMS adjusts the following Shared Savings Program calculations, as applicable, to exclude all Medicare Parts A and B fee-for-service

payment amounts on DMEPOS claims (claim types 72 and 82) associated with a HCPCS code specified in paragraph (b) of this section for the period specified in paragraph (d) of this section:

(1) Calculation of Medicare Parts A and B fee-for-service expenditures for an ACO's assigned beneficiaries for all purposes including the following: Establishing, adjusting, updating, and resetting the ACO's historical benchmark and determining performance year expenditures.

(2) Calculation of fee-for-service expenditures for assignable beneficiaries as used in determining county-level fee-for-service expenditures and national Medicare fee-for-service expenditures, including the following calculations:

(i) Determining average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area according to §§ 425.601(c) and 425.654(a) for purposes of calculating the ACO's regional fee-for-service expenditures.

(ii) Determining the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries for purposes of the following:

(A) Truncating assigned beneficiary expenditures used in calculating benchmark expenditures under § 425.652(a)(4), and performance year expenditures under §§ 425.605(a)(3) and 425.610(a)(4).

(B) Truncating expenditures for assignable beneficiaries in each county for purposes of determining county fee-for-service expenditures according to §§ 425.601(c)(3) and 425.654(a)(3).

(C) Truncating expenditures for assignable beneficiaries for purposes of determining truncated national per capita fee-for service expenditures for purposes of calculating the ACPT according to § 425.660(b)(3).

(iii) Determining truncated national per capita fee-for-service Medicare expenditures for assignable beneficiaries for purposes of calculating the ACPT according to § 425.660(b)(3).

(iv) Determining national per capita expenditures for Parts A and B services under the

original Medicare fee-for-service program for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark according to § 425.656(c)(3) and capping the prior savings adjustment according to § 425.658(c)(1)(ii).

(v) Determining national growth rates that are used as part of the blended growth rates used to trend forward BY1 and BY2 expenditures to BY3 according to § 425.652(a)(5)(ii) and as part of the blended growth rates used to update the benchmark according to §§ 425.601(b)(2) and 425.652(b)(2)(i).

(3) Calculation of Medicare Parts A and B fee-for-service revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track as specified in § 425.605(d).

(4) Calculation of total Medicare Parts A and B fee-for-service revenue of ACO participants and total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO, as defined under § 425.20, and determining an ACO's eligibility to receive advance investment payments according to § 425.630.

(5) Calculation or recalculation of the amount of the ACO's repayment mechanism arrangement according to § 425.204(f)(4).

(d) *Period of adjustment*. CMS adjusts the Shared Savings Program calculations specified in paragraph (c) of this section for significant, anomalous, and highly suspect billing activity identified pursuant to paragraph (b) of this section for calendar year 2023, when calendar year 2023 is either a performance year or a benchmark year.

(e) *Adjustments for growth rates used in calculating the ACPT*. In addition to adjustments described in paragraph (c) of this section, CMS makes adjustments for payments associated with a HCPCS code specified in paragraph (b) of this section for BY3 in projecting per capita growth in Parts A and B fee-for-service expenditures, according to § 425.660(b)(1), for purposes of calculating the ACPT for agreement periods beginning on January 1, 2024.

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[FR Doc. 2024-14601 Filed: 6/28/2024 4:15 pm; Publication Date: 7/3/2024]