any new requirements or change the substantive requirements. Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866(58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023), and was therefore not subject to Executive Order 12866 review.

B. Paperwork Reduction Act (PRA)

This action does not contain any new information collection burden under the PRA, 44 U.S.C. 3501 *et seq.* OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control number 2070–0162 (EPA ICR No. 1884.15). This action does not create any new reporting or recordkeeping obligations, and does not otherwise change the burden estimates that were approved.

C. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA, 5 U.S.C. 601 *et seq.* The RFA applies only to rules subject to notice and comment rulemaking requirements under the APA, 5 U.S.C. 553, or any other statute. This rule is not subject to notice and comment requirements under the APA because the Agency has invoked the APA ''good cause'' exemption (see Unit II.).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million (in 1995 dollars and adjusted annually for inflation) or more as described in UMRA, 2. U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action will not have federalism impacts as defined in Executive Order 13132 (64 FR 43255, August 10, 1999) because this action will not have substantial direct effects on States, on the relationship between the Federal Government and States, or on the distribution of power and responsibilities between the Federal Government and States.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action will not have tribal implications as defined in Executive Order 13175 (65 FR 67249, November 9, 2000) because this action will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it does not address environmental health or safety risks disproportionately affecting children. Since this action does not concern human health, EPA's 2021 Policy on Children's Health also does not apply.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have any adverse effect on the supply, distribution or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve technical standards under the NTTAA section 12(d), 15 U.S.C. 272.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

EPA believes that this type of action does not concern human health or environmental conditions and therefore cannot be evaluated with respect to potentially disproportionate and adverse effects on communities with environmental justice concerns in accordance with Executive Orders 12898 (59 FR 7629, February 16, 1994) and 14096 (88 FR 25251, April 26, 2023).

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.,* and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This does not meet the criteria set forth in 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 711

Environmental protection, Chemicals, Confidential Business Information (CBI), Hazardous materials, Importer, Manufacturer, Reporting and recordkeeping requirements.

Dated: September 23, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, for reasons set forth in the preamble, EPA amends 40 CFR part 711 as follows:

PART 711—[AMENDED]

■ 1. The authority citation for part 711 continues to read as follows:

Authority: 15 U.S.C. 2607(a).

■ 2. Revise and republish § 711.20 to read as follows:

§ 711.20 When to report.

All information reported to EPA in response to the requirements of this part must be submitted during an applicable submission period. The 2024 CDR submission period is from June 1, 2024, to November 22, 2024. Subsequent recurring submission periods are from June 1 to September 30 at 4-year intervals, beginning in 2028. In each submission period, any person described in § 711.8 must report as described in this part.

[FR Doc. 2024–22060 Filed 9–26–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 425

[CMS–1799–F]

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: Final rule.

SUMMARY: This final 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. In this final rule, we respond to public comments we received on the proposal to mitigate the impact of significant, anomalous, and highly suspect billing activity on Medicare Shared Savings Program financial calculations in calendar year (CY) 2023.

DATES: These regulations are effective on October 15, 2024.

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

SUPPLEMENTARY INFORMATION:

CPT (Current Procedural Terminology) Copyright Notice

Throughout this final rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2019 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

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 final 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.

We published a proposed rule entitled ''Significant, Anomalous, and Highly Suspect Billing Activity on Medicare Shared Savings Program Financial Calculations in Calendar Year 2023, which appeared in the July 3, 2024 **Federal Register** (89 FR 55168) (hereinafter referred to as the ''SAHS

billing activity proposed rule''). In the SAHS billing activity proposed rule, we proposed to use our authority under sections 1899(d)(1)(B)(ii) and 1899(i)(3) of the Act to make adjustments to the Shared Savings Program's benchmark and program expenditure calculations, among other calculations, to remove payment amounts for codes displaying significant, anomalous, and highly suspect (SAHS) billing activity in CY 2023. We proposed this rule to mitigate the impact of SAHS billing activity for selected intermittent urinary catheter supplies on Shared Savings Program calculations.

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

In the SAHS billing activity proposed rule (89 FR 55169), we explained that 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.

In early 2023, CMS detected a suspicious increase in billing for urinary catheters. Using our authority to suspend payments, CMS quickly stopped payment on almost all of these claims and began investigating the suppliers who were billing.[1 2] Since then, the top 15 billers of suspicious catheter claims have had their Medicare enrollment revoked.

As explained in the proposed rule, 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 Unified Program Integrity Contractors, to investigate health care fraud activities, such as those involving urinary catheter supplies, that exploit the Medicare program.

The observed DMEPOS billing volume for intermittent urinary catheters in CY 2023 represents 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.

We explained that 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 explained that we shared (and continue to share) the concerns recently raised by some ACOs and other interested parties that SAHS billing activity for 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 would 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 would

[1] In the preamble to the proposed rule, we stated our investigation into the matter was ongoing, and that we had made referrals to law enforcement, recouped payments, and terminated certain suppliers from the Medicare program (89 FR 55169). We clarify in this final rule that, CMS stopped payment to the suppliers for these claims, thus no recoupments were needed.

[2] As claim suspensions are the ''withholding of payment . . . from a provider or supplier of an approved Medicare payment amount before a determination of the amount of the overpayment exists, or until the resolution of an investigation of a credible allegation of fraud,'' 42 CFR 405.370, amounts suspended are considered payable under the Shared Savings Program.

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 would 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, would 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 would experience windfall gains (for example, higher shared savings or lower or no shared losses).

In the SAHS billing activity proposed rule (89 FR 55170), we explained that 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.[3] 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.[4] 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 catheters, is not only inequitable but would dramatically increase the level of risk associated with participation, making the Shared Savings Program unattractive.

For these reasons, we determined it was 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. In this Background section of the final rule, we summarize and respond to general comments we received related to CMS undertaking notice and comment rulemaking on this topic. In the following sections of this final rule, we summarize and respond to public comments we received on the specific proposals outlined in the SAHS billing activity proposed rule and discuss our final policies after taking into consideration the public comments.

Comment: Most commenters expressed broad support for the proposed rule or general support for the proposed rule with additional recommendations. Many commenters stated their ''strong,'' ''full,'' or ''general'' support for the proposed rule and urged CMS to finalize the proposals. Many commenters also commended CMS for taking action to address concerns raised by ACOs and other interested parties about the impact of SAHS billing activity for the catheter codes, and many also characterized CMS's attention to the matter as ''prompt,'' ''swift,'' ''timely,'' or ''responsive to stakeholder input.'' No commenters expressed general opposition to the proposed rule.

Supportive commenters offered a variety of reasons why they believed undertaking rulemaking was appropriate to mitigate SAHS billing activity for selected catheter codes. Many commenters agreed that the proposals would ensure the accuracy, fairness, or integrity of Shared Savings Program financial calculations. One commenter described the proposal as a ''crucial step'' and a ''necessary and well-supported measure'' to ensure or enhance the accuracy, fairness, and integrity of financial calculations in the Shared Savings Program. A couple of commenters agreed with CMS that addressing the SAHS billing activity promptly is essential to preventing inaccurate and inequitable payment and repayment obligations for ACOs, with one also stating that the proposals will help ''rectify the financial distortions'' caused by the SAHS billing activity for the catheter codes. One commenter stated that the proposed rule highlights CMS's dedication to addressing fraud as well as ensuring that the Shared Savings Program operates effectively while fostering a more transparent and equitable system. Other commenters stated that the proposals would improve sustainability of the Shared Savings Program. For instance, one commenter claimed that an ''accurate and fair reconciliation process will ensure that health systems, ACOs and providers continue to participate in value-based care models with CMS in the future,'' and a couple of other commenters asserted that the proposals will help keep ACOs in the program. Another commenter said that the proposals are important to ''maintain a strong, predictable ACO program,'' and another mentioned that not addressing the SAHS billing activity could lead to ACOs leaving the program.

Response: We thank commenters for their support for CMS's actions to undertake notice and comment rulemaking to mitigate the impact of SAHS billing activity on Medicare Shared Savings Program financial calculations in CY 2023. We agree with the commenters who stated that mitigating the impact of SAHS billing activity in CY 2023 is important for promoting continued integrity and fairness and improving the accuracy of Shared Savings Program financial calculations. Additionally, addressing the SAHS billing activity promptly is essential to preventing inaccurate and inequitable payment and repayment obligations for ACOs. We agree with the commenters that this course of action will in turn support the sustainability of the Shared Savings Program.

Comment: Commenters addressed the role that ACOs play in the identification of SAHS billing activity or fraud, waste, and abuse in Medicare. Many commenters representing ACOs stated that their ACO reported SAHS billing activity for catheter codes to regulatory

[3] 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.*

[4] 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.*

or law enforcement agencies, with one adding that ''as an ACO, it is our responsibility to report suspect fraud to authorities,'' and another stating that they will be submitting documentation about suspect claims for their ACO beneficiaries to the HHS Office of Inspector General (HHS–OIG). Other commenters credited ACOs for playing a role in identifying the SAHS billing activity for catheter codes in CY 2023. One commenter stated their belief that ACOs are ''well positioned to detect anomalous billing'' given their ongoing and in-depth analysis of claims and utilization data, and others noted that the HHS–OIG identified ACOs as sources to uncover potential fraud, waste, and abuse by identifying patterns of unusual billing. One commenter stated they will continue to monitor for SAHS billing activity. Some commenters stated there are opportunities to improve how ACOs report fraud or better educate ACOs on the processes CMS and HHS–OIG undertake to investigate fraud.

Response: We agree that ACOs are well positioned to support monitoring efforts that will improve the integrity of the Medicare program. ACOs have tools to detect unusual or suspect billing among their assigned beneficiary population through data reports provided by CMS and through their own data systems. We appreciate ACOs' efforts to alert CMS to potential impacts on their PY 2023 expenditures because of the increased catheter billings. ACOs are encouraged to report potential fraud or abuse by submitting a complaint to the CMS Center for Program Integrity (CPI), Fraud Investigations Group (FIG), Division of Provider Investigations (DPI) at *https://dpi.intake@cms.hhs.gov.* ACOs can also report potential fraud or abuse by submitting a complaint to the OIG website,[5] OIG hotline at 1–800–HHS–TIPS (1–800–447–8477), TTY at 1–800–377–4950, by fax at 1–800–223–8164, or by mailing to: Office of Inspector General ATTN: OIG HOTLINE OPERATIONS P.O. Box 23489 Washington, DC 20026. ACOs suspecting healthcare fraud, waste, or abuse are encouraged to visit the CMS CPI website[6] at *https://www.cms.gov/medicare/medicaid-coordination/center-program-integrity,* for more information.

As described above, CMS continues to investigate the matter and we have taken initial actions in response. We have made referrals to law enforcement and terminated certain suppliers from the Medicare program. CMS also continues to work closely with the HHS–OIG and Department of Justice, as well as our Unified Program Integrity Contractors, to investigate health care fraud activities, such as those involving urinary catheters, that exploit the Medicare program. We also undertook this 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.

Comment: A couple of commenters appeared to interpret the proposals as new rules for providers to follow in their billing practices. One commenter, while stating their support for preventing ''fraudulent practices that jeopardize the program's sustainability and unfairly impact the financial calculations for participating providers,'' cautioned that CMS should not put in place ''compliance requirements that overly burden honest providers'' and recommended that CMS provide additional support and resources to help providers understand and comply with the new requirements. The other commenter, while characterizing the proposed rule as ensuring fairness, accuracy in financial calculations, fraud prevention, and cost control, also stated that one potential drawback was that ''some providers might feel unfairly targeted or burdened by additional scrutiny and adjustments.''

Response: We clarify that rules or requirements for providers in how they bill or are paid by Medicare are beyond the scope of this proposed rule. The proposed changes do not impose new rules or requirements related to provider billing and payment. The proposed changes are specific to ACOs and Shared Savings Program calculations to mitigate the impact of SAHS billing activity in CY 2023 that would otherwise be included in Shared Savings Program expenditure and revenue calculations under the current regulations governing the Shared Savings Program.

II. Provisions of the Regulations

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

As we explained in the SAHS billing activity proposed rule (89 FR 55170), 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 would be addressed during 2024.[7]

We explained that 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 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.

Comment: Many commenters agreed with CMS' determination that HCPCS codes A4352 and A4353 displayed SAHS billing activity in CY 2023. Multiple commenters specifically referred to HCPCS codes A4352 and A4353 when expressing their support for CMS' proposals, with many others stating their support with less specificity—for instance stating their support for CMS to address billing activity associated with ''catheters,''

[5] *https://oig.hhs.gov/fraud/report-fraud/.*

[6] *https://www.cms.gov/medicare/medicaid-coordination/center-program-integrity/reporting-fraud.*

[7] 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.*

''the HCPCS codes,'' or ''the catheter codes.''

Some commenters supported their agreement that the two catheter codes displayed SAHS billing activity by including data to highlight how billing activity for the selected catheter codes impacted their ACO expenditures, and other commenters offered data on the impact on national assignable FFS expenditures.

Response: We appreciate the specific feedback from commenters and agree that the observed DMEPOS billing volume for 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*) in CY 2023 represents SAHS billing activity.

Comment: One commenter stated they identified and reported ''anomalous billing activity'' for an additional catheter billing procedure code (HCPCS code A4351) and that the proposal to identify HCPCS codes A4352 and A4353 as SAHS billing activity in CY 2023 does not fully address the potential ''bias'' in financial calculations for their ACO of SAHS billing activity for catheter services.

Response: We defined SAHS billing activity in the proposed rule (89 FR 55169) to mean 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.

In developing the proposed rule, we assessed the impact of an increase in billing to Medicare for intermittent urinary catheter services on DMEPOS claims in CY 2023. We determined that billing activity for HCPCS codes A4352 and A4353 was SAHS billing activity while A4351 was not. HCPCS codes A4352 and A4353 were billed at significantly higher rates in CY 2023 compared to CY 2022 (claims increasing by 163 percent 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). We also determined that the change in claim volume was significant and unexplained, and if not addressed, would cause inaccurate and inequitable payments and repayment obligations in the Shared Savings Program.

Our assessment found that billing activity for HCPCS code A4351, however, was not SAHS billing activity. Compared to catheter codes A4352 and A4353, billing for HCPCS code A4351 exhibited a much smaller increase between CY 2022 and CY 2023, with claims rising by approximately 16 percent. Also, unlike A4352 and A4353, where the unexplained billing increase represented the vast majority of spending on those codes in CY 2023, the billing increase for A4351 represented a small proportion of total billing activity for the code in CY 2023. We determined that this level of billing did not represent a significant claims increase with national or regional impact that unexpectedly deviated from historical utilization trends. We also determined that the increase in utilization of HCPCS code A4351 was not clearly a billing level that was representative of activity that would cause significantly inaccurate and inequitable payments and repayment obligations in the Shared Savings Program if not addressed. This conclusion was based on our finding that the increase in billing for the code was so small relative to overall spending for most ACOs and to overall national or regional spending that it would be unlikely to have significant program-wide impacts on payment and repayment obligations. However, we will continue to monitor the billing activity with this code in partnership with our program integrity colleagues.

Comment: Some commenters stated that, in addition to catheter codes, codes for skin substitutes exhibited SAHS billing activity in CY 2023. Other commenters urged CMS to assess or evaluate whether additional codes warranted adjustment in Shared Savings Program calculations and cited increases in billing for skin substitutes as an example.

Response: We assessed the impact of an increase in billing to Medicare for skin substitutes and determined that the billing activity for these services was not SAHS billing activity.[8] Specifically, we found that increases in billing activity for skin substitutes were explained by the deviation in Local Coverage Determinations (LCDs) across Medicare Administrative Contractors and the variety of innovative products which fall under this area, which made these services more available in CY 2023.[9] However, we will continue to monitor this area and work with our program integrity partners. Furthermore, as part of our larger strategy to address SAHS billing activity and improper payments on Shared Savings Program financial calculations, CMS has proposals in the CY 2025 PFS proposed rule, including (respectively): to adjust Shared Savings Program calculations to mitigate the impact of SAHS billing activity occurring in CY 2024 and subsequent calendar years, and to establish a calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations upon reopening a payment determination.

Comment: Some commenters identified additional codes or services that they believed exhibited SAHS billing activity in CY 2023 or warranted additional evaluation by CMS. Specifically, commenters mentioned: glucose monitoring, laboratory services, telemedicine, ventilators, diabetic supplies, collagen dressings, and other unspecified DMEPOS supplies billed by the same suppliers involved in the anomalous catheter billing. Several commenters suggested that the billing activity associated with some of these codes had regional, rather than national impacts, and there would be a detrimental impact to ACO savings unless accounted for by CMS.

Response: We appreciate commenters notifying us of their concerns over billing activity in CY 2023 for other services; however, only the billing for urinary catheter services met the definition of SAHS billing activity as finalized in this rule with respect to CY 2023. We defined SAHS billing activity in the proposed rule to mean 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

[8] Refer to the definition of SAHS billing activity stated elsewhere in this final rule.

[9] Medicare Administrative Contractors also released a proposed LCD on April 25, 2024 for skin substitute grafts/cellular and tissue-based products for the treatment of diabetic foot ulcers and venous leg ulcers. See *https://www.cms.gov/newsroom/press-releases/cms-statement-proposed-local-coverage-determination-lcd-skin-substitute-grafts/cellular-and-tissue.*

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 (89 FR 55169). 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. Unlike the two urinary catheter codes, some of the other services mentioned by commenters were too broad in nature to be considered SAHS billing activity. While a group of codes may exhibit patterns that could constitute SAHS billing activity, each individual code must still exhibit SAHS billing activity for it to be considered under the definition of SAHS billing activity we relied on in our proposal. Some of the commenters' concerns span entire claim types or hundreds of procedure codes, suggesting that SAHS billing activity existed only in aggregate and not for any individual code. For the other services suggested by commenters that were more specific in nature, the facts necessary to support a determination of SAHS billing activity had not been developed at the time of this rulemaking.

We narrowly crafted the definition of SAHS billing activity in part out of fairness to ACOs. Both under this rule and a related proposal in the CY 2025 Medicare Physician Fee Schedule (PFS) (89 FR 61909 through 61916) to address future instances of SAHS billing activity, we are mindful of equitable concerns that may arise from CMS revising standards for the calculation of an ACO's financial performance after the start of a performance year or, in the case of CY 2023, the completion of the performance year. More specifically, we described that for billing activity to be considered SAHS, the billing activity would need to show a significant claims increase either in volume or dollars and have national or regional impact. These high standards are appropriate because the remedy we are using to correct for SAHS billing activity is the broad exclusion of the relevant CPT or HCPCS code from certain important financial calculations, and this could have mixed impact on Shared Savings Program ACOs. Without these high standards, ACOs are more likely to be held liable for losses that they would not be otherwise be accountable for or have a reduction in or loss of their shared savings.

We remain committed to evaluating other cases when improper payments may have been made and assessing the impact on Shared Savings Program calculations. For these reasons, we proposed two policies of general applicability in the CY 2025 PFS (89 FR 61596) to address instances of improper billing and payments. The first proposal in the CY 2025 PFS proposed rule would allow CMS to address instances of SAHS billing activity occurring in CY 2024 or subsequent years prior to financially reconciling the performance year in which the activity occurred (89 FR 61909 through 61916). Under the proposal, following the end of each calendar year, we would determine whether any codes exhibited SAHS billing activity (defined as described elsewhere in this final rule) and adjust expenditure and revenue calculations to exclude payment amounts. We would make these adjustments both when the calendar year serves as a benchmark or performance year. Additionally, under the proposed policy, we would adjust historical benchmarks used to reconcile the performance year when the SAHS activity occurred to remove payment amounts for the codes from benchmark year expenditures.

The second proposal would provide relief to ACOs that are affected by instances of fraud or other improper payments that may not meet the definition of SAHS billing activity (89 FR 61892 through 61909) or for which there is not enough information available at the close of the affected calendar year to make a determination of whether SAHS billing activity occurred. Under this proposal, an ACO could request the reopening of its previously completed financial reconciliation results so that they can be reevaluated for inaccuracies as a result of new information being available. In the CY 2025 PFS proposed rule (89 FR 61596) we invited interested parties to comment on these proposals.

Comment: Several commenters also urged CMS to consider HCPCS codes A4352 and A4353 as displaying SAHS billing activity for time periods beyond CY 2023. Multiple commenters urged CMS to remove—or assess whether to remove—the selected catheter codes from CY 2024, with some referencing CMS's proposals in the CY 2025 PFS rule related to mitigating SAHS billing activity occurring in CY 2024 and subsequent years. One of these commenters also urged CMS to assess whether billing for the selected catheter codes in CY 2022 constitutes SAHS billing activity and recommended that CMS and HHS–OIG review potentially fraudulent claims for other DMEPOS provided between 2022 and 2024. One commenter expressed concerns that limiting the scope of the adjustment to the selected catheter claims and to the CY 2023 time period would not fully address the ''bias'' affecting its ACO.

Response: With respect to any billing increases of the selected catheter codes in CY 2024, we note that this is outside the scope of this final rule. However, in the CY 2025 PFS proposed rule (89 FR 61909 through 61916), we proposed policies to mitigate the impact of SAHS billing activity occurring in CY 2024 or subsequent calendar years. Specifically, we proposed that CMS may determine at its sole discretion that the billing of specified HCPCS or CPT codes represents SAHS billing activity in CY 2024 or subsequent calendar years that warrants adjustments to Shared Savings Program calculations.

With respect to performance years prior to CY 2023, we note that CMS has already completed financial reconciliation for those years, and therefore the policy approach proposed in the SAHS billing proposed rule and adopted in this final rule would not address any billing increases of catheter codes. As discussed elsewhere in this final rule, the Shared Savings Program reopening policy proposal in the CY 2025 PFS proposed rule (89 FR 61892 through 61909) presents a mechanism by which issues affecting already reconciled performance years may be addressed.

Final Action: After consideration of public comments, we are finalizing our proposal to specify in the Shared Savings Program regulations at § 425.670(b) 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 would cause significantly inaccurate and inequitable payments and repayment obligations in the Shared Savings Program if not addressed.

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 the SAHS billing activity unaddressed and the limitations with using an approach available under the current regulations (as we describe elsewhere in this rule), we proposed 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 provisions 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 proposed to adjust the benchmark to remove payments for the specified catheter codes from the determination of benchmark expenditures. We proposed 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 proposed 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) [10] 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 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 recognizes 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.[11] Second, the proposed policy includes calculations related to truncated national per capita expenditures used in determining the

[10] 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*).

[11] 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.

ACPT as described in § 425.660(b)(3) that are not included in § 425.611(c).[12]

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 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.[13] 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 expected 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 ensures that the projected growth rates in future years (for which billing for the selected catheter claims is expected to revert to typical levels) will not be biased.

As noted in the Regulatory Impact Statement (section V. of this final 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.

In the SAHS billing activity proposed rule (89 FR 55172), we acknowledged 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 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 explained that 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 explained that 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 V. of this final 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

[12] 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.

[13] 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.*

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 prolonged delay to the issuance of initial determinations and earned performance payments for PY 2023 would outweigh 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 rule relies 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 authorized by section 1899(i)(3) of the Act. Specifically, we 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 [14] and determinations of eligibility for advance investment payments.[15] Section 1899(i)(3) of the Act requires that we determine that the alternative payment methodology adopted under that provision will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures. The adjustments we proposed, which would remove payment amounts for codes with identified SAHS billing activity from the specified Shared Savings Program calculations specified in a 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 their assigned beneficiary populations.

As described in the Regulatory Impact Statement (section V. of this final 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 will 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 will 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 V. of this final 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.

This final rule will be applied retroactively, as it affects a performance year that has already been completed (PY 2023) and a performance year that has already started (PY 2024). More specifically, we are retroactively adjusting 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 are used to determine ACO financial performance for PY 2024 and subsequent years of an ACO's agreement period. 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 these policies 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 financial risk for costs that are outside their control and were 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 to negatively impact ACOs financially when the Shared Savings Program was established.[16] 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. Loss of faith in CMS's ability to effectively administer the Shared Savings Program by ACOs, providers, and the public would likely substantially reduce ACO and provider participation in the program. Reduced participation, in turn, would significantly diminish the savings generated to the Medicare Trust Funds and quality of care improvements resulting from the Program and reduce the coordination of care performed for Medicare beneficiaries when obtaining items and services from ACO providers and suppliers.[17] For these reasons, it

[14] 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.

[15] See § 425.630(b).

[16] *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.

[17] *See, for example,* Medicare CY 2023 PFS final rule, 87 FR 70195 through 70196 (estimating that the addition of new low revenue ACOs would

Continued

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 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 proposed 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 (89 FR 55174). We proposed 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 proposed 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 proposed 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 proposed 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.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Many commenters provided input on the methodology outlined in the proposed rule to mitigate the impact of SAHS billing activity occurring in CY 2023. Most of these commenters stated their support for removing payment amounts for the specified catheter HCPCS codes in CY 2023 from the specified Shared Savings Program expenditure and revenue calculations.

Response: We thank the commenters for their support of the proposed adjustments to Shared Savings Program calculations. We interpret the commenters' general descriptions of our proposed adjustments and broad support for the proposed rule as supportive of all the adjustments to Shared Savings Program calculations we proposed in the proposed rule (89 FR 55171 through 55172) and described elsewhere in this section of the final rule.

Comment: Many supportive commenters specified their support for removing "all" Medicare Part A and B payment amounts related to the selected catheter codes, or for removing Medicare Part A and B payment amounts for the selected catheter codes "by any supplier" or "across all suppliers."

Response: We thank the commenters for their support of our proposal to remove payment amounts for the selected catheter HCPCS codes on DMEPOS claims submitted by any supplier. By removing all catheter HCPCS payments, we ensure that all of the SAHS billing activity in CY 2023 for the selected catheter codes will be removed from any calculations used to financially reconcile ACOs for PY 2023 or in future performance years when CY 2023 serves as a historical benchmark year for an ACO. This approach ensures that ACO expenditures, as well as regional and national expenditures, are not distorted by payment amounts for SAHS billing activity beyond the ACOs' control.

Comment: Many commenters supported the proposal to apply the adjustments when CY 2023 is a benchmark year for ACOs in the agreement periods starting in 2024, 2025, or 2026. A couple of commenters stated their support for removing payment amounts for the specified catheter codes from the determination of "benchmark expenditures" or from "CY 2023 benchmark expenditures" without specifying which agreement periods these adjusted benchmark expenditures would be used to reconcile.

Response: We thank the commenters for their support of the proposed adjustments to Shared Savings Program calculations when CY 2023 serves as a benchmark year. We explain in this section of the final rule that the adjustments would apply to BY 2023 in calculating the historical benchmark for agreement periods beginning in 2024, 2025 and 2026. In contrast, as we also explain in this section of this final rule, we opted not to propose adjusting historical benchmarks that will be used for PY 2023 financial reconciliation to remove all payment amounts for the selected codes from benchmark year expenditures. That means, for example, that when performing financial reconciliation for PY 2023 for an ACO that started an agreement period in 2023, we will not adjust the ACO's historical benchmark to exclude payment amounts for the selected codes from expenditures for BYs 2020 through 2022.

While some commenters expressed high level support for adjusting benchmark expenditures, we interpret these comments as supportive of all the adjustments to Shared Savings Program calculations we proposed in the proposed rule (89 FR 55171 through 55172) and described elsewhere in this section of the final rule.

Comment: Some commenters specifically supported the proposal to exclude all Medicare Parts A and B payment amounts for the selected catheter codes on DMEPOS claims when CY 2023 is used to calculate the national-regional blended update to the benchmark used in determining financial performance for PY 2023. A couple of these commenters explained that this proposal, alongside the proposals to adjust ACO expenditures when CY 2023 serves as a performance year and a benchmark year, was "a comprehensive approach" and "the most straightforward." One commenter stated that the proposals will promote accuracy and validity of the data used for trending benchmarks.

Response: We thank commenters for their support for the proposal to remove payment amounts when CY 2023 is used to calculate the national-regional blended update to the benchmark. We agree with the comments that removing payment amounts in calculating both ACO expenditures and update factors is a comprehensive approach, as it will ensure that no SAHS billing activity for the selected catheter codes is included in the national-regional blended update factor and promotes symmetry when

produce $3 billion in net savings over a 5-year period).

comparing an ACO's performance year expenditures to its updated benchmark.

Comment: Some commenters also expressed support specifically for the proposal to exclude all Medicare Parts A and B payment amounts for the selected catheter codes on DMEPOS claims from CY 2023 in revenue calculations, or from calculations to determine revenue status and repayment mechanism amounts in the application and change request cycle for ACOs applying to enter a new agreement period beginning on January 1, 2025 or continue their participation in the program in PY 2025.

Response: We thank commenters for their support of the proposal.

Comment: Two commenters expressed concern that some ACOs may be financially disadvantaged by the proposed adjustments to Shared Savings Program calculations, with one emphasizing that the approach would harm ACOs that have DME services below national and regional benchmark trends and thus would have more dollars removed from their benchmark than from their own expenditures. The commenters encouraged CMS to ensure that ACOs are not adversely impacted financially by the adjustments. They requested that—due to the retroactive nature of the policy—CMS should hold ACOs harmless for the removal of the codes or limit the impact of the policy using a guardrail (for example, 0.02 percent in either direction) for PY 2023 financial calculations. One also expressed concern that ACOs could be disadvantaged if CMS removes the selected catheter codes from BY 2023 but not from future performance years that are reconciled using a historical benchmark that includes BY 2023.

Response: We decline to adopt an approach that would have CMS perform two versions of Shared Savings Program calculations—one that makes adjustments for SAHS billing activity and one that does not—and then issuing initial determinations based on the version of the calculations that would result in a ACO maximizing their shared savings or minimizing their shared losses for PY 2023 or based on calculations that impose a guardrail that limits the impact of the proposed policy. As we explained elsewhere in this final rule, the SAHS billing activity for the selected catheter codes would cause significantly inaccurate and inequitable payments and repayment obligations if not addressed. It would be inequitable for ACOs to be held accountable for SAHS billing activity that occurred among their assigned population in the performance year. It would also be inequitable to allow other ACOs whose assigned populations were less affected by SAHS billing in CY 2023 to benefit from the inclusion of these expenditures in the PY 2023 benchmark update factors. Such ACOs would receive an inaccurate updated benchmark as a result of SAHS billing activity affecting national or regional expenditures. Allowing either source of inequity or imposing an artificial limit on the impacts of excluding the SAHS billing activity would undermine the integrity, fairness and accuracy of Shared Savings Program calculations.

As part of our final policy, we also decline to remove the selected catheter codes from future performance years that are reconciled using a historical benchmark that includes BY 2023. For example, when performing financial reconciliation for PY 2024 for an ACO with benchmark years 2021 through 2023, we will only exclude payment amounts for the selected catheter codes from BY 2023 expenditures and not from BY 2021, BY 2022, and PY 2024 expenditures. As we explained in the proposed rule (89 FR 55172), historical billing for the selected catheter HCPCS codes has consistently been relatively low, including in recent years. As noted in the Regulatory Impact Statement (section V. of this final 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.

Comment: A couple of commenters suggested CMS should modify its approach to mitigating the impact of SAHS billing activity from the proposal. One commenter expressed concern over any approach that would remove catheter codes from the national component of the update factor used to calculate the benchmark for PY 2023 but not from the regional component of the update factor. The second commenter stated their suspicion that the impacts of SAHS billing activity for the catheter codes varies widely across ACOs and explained their "hope" that the methodology for adjusting historical benchmarks will account for individual and regional variation in this element, so it does not adversely impact benchmarks of some over others.

Response: We proposed 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 will perform this adjustment 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.[18] That is, payment amounts will be removed from both the national component and the regional component of the national-regional blended update factor. By applying this adjustment to both components of the update factor, the adjustment will account for any individual and regional variation of SAHS billing activity for the catheter codes so that the impact of the exclusion of the catheter codes on an ACO is dependent on the degree to which SAHS billing activity for the catheter codes impacted the ACO's region and the ACO's beneficiaries. Additionally, we will perform this adjustment when CY 2023 serves as a benchmark year.

Comment: Many commenters in support of the proposals expressed differing views on the anticipated impact of the proposed changes on Shared Savings Program ACOs' financial performance. Many supportive commenters suggested the proposed changes would be financially advantageous for ACOs or that they will improve the accuracy of CMS' evaluation of the ACO's financial performance. One commenter stated that not finalizing the proposed changes and including payment amounts for SAHS billing activity for catheter codes would have a "severely inappropriate impact" on Shared Savings Program calculations and might lead to a loss of shared savings for some ACOs. Several commenters characterized the proposals as helping to hold ACO's "harmless" for SAHS billing activity for the catheter codes on ACO expenditures, with one stating their belief that ACOs should not be responsible for costs "that were not associated with the care of their beneficiaries" and another stating that ACOs should not be held responsible for "anomalous Medicare spending" beyond their control. One commenter stated that the proposals are vital to supporting ACOs in maintaining their financial stability, and another stated that the proposals are vital to ensuring that ACOs are not "unfairly penalized for expenses beyond their control." Other commenters stated that SAHS

[18] For PY 2023, the only portion of the financial reconciliation calculations that retain the codes is the calculation of historical benchmarks, excluding the national-regional update factor.

billing activity ''weakens the integrity'' of the Shared Savings Program and can have a detrimental impact on organizations' financial reconciliation.

Some supportive commenters from ACOs described the anticipated impact the SAHS billing activity would have on their own ACO's financial performance absent the adjustments to calculations. One commenter stated their belief that the inclusion of payment amounts for the catheter codes would ''damage the integrity'' of their ACO's PY 2023 financial reconciliation. A few commenters stated that without these adjustments their ACOs may not share in savings, shared savings could be negatively impacted, or their ACOs would have a high probability of being liable for shared losses. One commenter stated that if payment amounts for the selected catheter codes were included, their ACO would have a high probability of being liable for shared losses. One commenter expressed their belief that removing payment amounts for the selected catheter codes will lead to a more accurate and true evaluation of their performance, and another stated that the proposals will have a substantial impact on their ACO's ''sustainability.'' A couple of commenters asserted their ACO expenditures were significantly impacted by the SAHS billing activity for the catheter codes.

Response: We agree with the commenters who stated the changes we are finalizing in this final rule will improve the accuracy and integrity of Shared Savings Program calculations. SAHS billing activity in CY 2023 for the selected catheter codes had a substantial impact on ACO expenditures as well as national expenditures. Failing to address SAHS billing activity that occurred in CY 2023 would jeopardize the integrity of the Shared Savings Program. Holding an ACO accountable for substantial losses due to the SAHS billing activity is not only inequitable but will dramatically increase the level of risk associated with participation, making the Shared Savings Program unattractive. We also agree with the many commenters who characterized the proposals as promoting continued integrity and fairness and improving the accuracy of Shared Savings Program financial calculations. Alternatively, proceeding with program operations using the current methodology that does not adjust for SAHS billing activity would cause significantly inaccurate and inequitable payments and repayment obligations.

Comment: Some commenters who expressed support for the proposed adjustments to Shared Savings Program calculations acknowledged the need for the application of the changes retroactively, with one stating that failure to do so would unfairly punish Shared Savings Program ACOs and potentially jeopardize the sustainability of the program.

A couple of commenters shared a concern about the retroactive nature of the changes, with one stating that ''unforeseen financially harmful calculations'' would be applied after the performance year has been completed with no time for ACOs to make any changes in decisions or operations. Both noted that ACOs used data received during the performance year (which would not have excluded payment amounts associated with the selected codes) to inform ACO activities, including strategies, resourced interventions, and participation decisions.

Response: We appreciate the support from some commenters for the retroactive applicability of this rulemaking, and we acknowledge the concern expressed by others. Any changes to calculations involving PY 2023 financial reconciliation or final historical benchmarks for ACOs starting new agreement periods on January 1, 2024, must have retroactive applicability because PY 2023 is already completed and PY 2024 has already begun. As we explain elsewhere in this section, applying the proposal retroactively is justifiable and consistent with our statutory authority because failing to apply the proposed changes retroactively would be contrary to the public interest. Failure to modify PY 2023 financial reconciliation and final historical benchmarks in the manner we describe in this rule 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.

Comment: Several commenters requested that CMS provide ACOs with information about the payment amounts excluded at the regional level or at both the regional and national level. A couple of commenters requested that CMS not remove claims associated with SAHS billing activity from the monthly claim and claim line feeds (CCLFs), requesting instead that CMS flag them.

Response: In order to promote transparency in calculations and address commenter's concerns, within program reports provided with PY 2023 financial reconciliation results, we will provide ACOs with the per capita amount of the two catheter codes removed from their performance year assigned beneficiary expenditures consistent with other spending categories. Medicare claim payment amounts for the two catheter codes will continue to be included in the monthly Part A, B and D Medicare CCLF files sent to ACOs.

Comment: Some commenters urged CMS to develop or strengthen policies and processes to monitor, report, and address SAHS billing activity should it occur in the future. One commenter, for example, recommended CMS ''build algorithms to concurrently identify fraud prior to making payments.'' Another commenter urged CMS to work with ACOs to improve the process for reporting suspected fraud, waste, and abuse. Several commenters also urged CMS to finalize policies to mitigate the impact of SAHS billing activity occurring in CY 2024 and subsequent years that were proposed in the CY 2025 PFS proposed rule.

Response: We thank commenters on their suggestions for strengthening policies and processes to monitor for potential fraud, waste, and abuse. We will share these comments with our program integrity colleagues, and we note that we have also provided information to ACOs on ways they can report potential fraud or abuse to CPI or HHS–OIG. We also thank commenters for their support for proposed policies to mitigate the impact of SAHS billing activity occurring in CY 2024 and subsequent years proposed in the CY 2025 PFS proposed rule. We will summarize and respond to comments submitted directly in response to that proposed rule within the CY 2025 PFS final rule.

Comment: Some commenters made recommendations for mitigating the impact of SAHS billing activity on Innovation Center models. Most of these commenters requested that the Center for Medicare and Medicaid Innovation (CMS Innovation Center) perform similar adjustments to mitigate SAHS billing activity for the catheter codes in the ACO Realizing Equity, Access, and Community Health (ACO REACH) Model, although several commenters expressed concerns that the approach being used by the ACO REACH Model would disadvantage ACOs. One commenter requested that the CMS Innovation Center exclude payment amounts for the catheter codes from the Bundled Payments for Care Improvement Advanced Model and the Comprehensive Care for Joint Replacement Model.

Response: The commenters' suggestions are beyond the scope of this rulemaking, which addresses adjustments to Shared Savings Program calculations to mitigate the impact of SAHS billing activity for selected catheter codes in CY 2023. The CMS Innovation Center did an assessment of the effects of SAHS billing in 2023 on each model. Determinations of whether action to address SAHS billing was necessary were made on a model-by-model basis.

Final Action: After consideration of public comments, we are finalizing our proposal to retroactively remove payment amounts for codes displaying SAHS billing activity in CY 2023 from Shared Savings Program expenditure and revenue calculations. Specifically, we are finalizing our proposal to add and reserve §§ 425.661 through 425.669 in subpart G and add a new section at § 425.670 to describe adjustments CMS will make to Shared Savings Program calculations to mitigate the impact of SAHS billing activity occurring in CY 2023. Section 425.670(b) specifies 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. Section 425.670(c) specifies the Shared Savings Program calculations for which CMS will 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 includes references to all relevant sections of the regulations in these provisions. In § 425.670(d), on the period of adjustment, we specify that CMS will 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 specify under § 425.670(e) that we will 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.

III. Reduction of the Comment Period and Reduction of the 30-Day Delay in Effective Date of This Final Rule

A. Reduction of the Comment Period to 30 Days

In the SAHS billing activity proposed rule (89 FR 55174), we explained that 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.[19] 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 has necessitated delaying key program operations that depend on CY 2023 data, pending the issuance of this final rule that specifies our final policy as informed by public comment on the SAHS billing activity proposed rule. We described in the 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).

We explained (89 FR 55174) that 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 conclusion of the performance year, and shortly thereafter issues performance payments to ACOs eligible to share in savings.[20] 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 rely on the orderly and timely calculation of financial reconciliation, and distribution of shared savings. We noted that modifications to Shared Savings Program financial methodology as proposed in the proposed rule necessitate delaying the delivery of financial reconciliation reports to ACOs, and issuance of performance payments to ACOs that have earned shared savings.

We further explained in the proposed rule (89 FR 55174) that delayed use of CY 2023 data would also impair administration of the Shared Savings Program in 2024 and 2025. CY 2023 data are 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. We explained that the proposed approach would help ensure the accuracy of the calculations used in determining ACO revenue status and repayment mechanism amounts. We noted that 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, and timely deliver initial advance investment payments for newly eligible ACOs. Substantial delays in change

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

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

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.

Finally, we explained (89 FR 55175) that modifications to Shared Savings Program financial methodology as proposed in the proposed rule would also necessitate delaying the delivery of final historical benchmark reports to ACOs. We expressed our recognition 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 and that 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 found that a 60-day comment period was both impracticable and contrary to the public interest (89 FR 55174 through 55176). For the reasons stated, we therefore reduced the comment period of the proposed rule to 30 days. We noted in the proposed rule that failing to use a 30-day comment period in lieu of a 60-day comment period would be impracticable and contrary to the public interest in part for the same reasons described in section II.B. of the proposed rule that failing to apply this rule retroactively to PY 2023 and PY 2024 would be contrary to the public interest. Additionally, we explained that 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.

We noted that 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 (89 FR 55175). A 60-day comment period would have likely necessitated 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.

We explained that 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 (89 FR 55175). 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. We noted that 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.

We explained that delaying adjudication of application and repayment mechanism decisions also would jeopardize or prevent CMS and ACOs starting performance year 2025 (89 FR 55175). 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.[21] 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, would impair 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, we noted that given the limited scope of the proposed rule, addressing a single issue through proposed changes to the Shared Savings Program regulations, a 30-day comment period was a reasonable amount of time for public inspection and comment (89 FR 55175). In advance of the SAHS billing activity proposed rule, many interested parties wrote to the Administrator requesting relief from SAHS billing activity, so they are familiar with this issue and would likely be ready to review the policy and impacts within the 30-day timeframe.

Furthermore, we explained that starting notice and comment rulemaking sooner to allow a 60-day comment period was impracticable (89 FR 55175 through 55176). As we described in the 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

[21] 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.*

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 the proposed rule, we found that a failure to reduce the comment period was impracticable and contrary to the public interest, and thus found the agency has good cause to set a 30-day comment period.

The modifications to the Shared Savings Program financial methodology that we are finalizing in this final rule, following the 30-day comment period, will 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 our use of the 30-day comment period will 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 will 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.

Comment: Some commenters requested that CMS extend deadlines by the same amount of time for the annual application and change request cycle, including deadlines for risk track selection, participant lists, and ACO PC Flex Model participation decisions.

Response: While we appreciate the interests of ACOs in requesting an extension of deadlines in the annual application and change request cycle by the same amount of time as the delay in issuance of performance year determinations, we are unable to delay deadlines by multiple weeks since it would delay application dispositions scheduled for early December until after the January 1, 2025, agreement period start date. This would require delaying the start of PY 2025 until sometime after January 1, 2025. This would, among other things, require CMS to propose policies for conducting financial calculations using a non-standard performance year, as was done to accommodate a July 1, 2019, performance year start date in the Share Savings Program final rule published in December 2018 (83 FR 67816). This would also create further delays and uncertainty for ACOs. A delay in finalizing participant lists would delay the publication of PY 2025 initial assignment lists, hindering ACOs' ability to effectively coordinate care for their assigned beneficiary populations.

A delay in the start of the Shared Savings Program's performance year also may have significant adverse consequences for ACO professionals participating in ACOs. Many Shared Savings Program tracks are Advanced Alternative Payment Models (APMs) for purposes of the Quality Payment Program APM incentive. Qualifying APM Participants (QPs) are not subject to the Merit-based Incentive Payment System reporting requirements or payment adjustments (though they may have separate and similar reporting obligations under the Shared Savings Program). *See* 42 CFR 414.1310(b)(1)(i) and (ii). For payment years through CY 2025, QPs also earn a lump-sum APM incentive payment based on estimated aggregate payments for covered professional services furnished during the preceding calendar year. *See* 42 CFR 414.1310; 414.1450. A reduction in the length of the Shared Savings Program's performance year could cause some ACO professionals to fail to achieve QP status.

While we are unable to modify Shared Savings Program applications deadlines for the reasons described previously in this final rule, we were able to extend the deadline for ACOs to apply to the ACO PC Flex Model from August 1, 2024, until August 23, 2024, as this delay would not delay Shared Savings Program application dispositions or the start of the Model.[22]

Furthermore, we are clarifying that we anticipate releasing PY2023 results in late October and making payments to ACOs in mid-November. Where possible, we will work to reduce delays and will proactively communicate with ACOs about changes in timelines.

B. Reduction of the 30-Day Delay in Effective Date of This Final Rule

In the proposed rule we explained that 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 (89 FR 55176). 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). We indicated in the proposed rule that, if CMS were to finalize a rule based on the proposed rule, we would strongly consider reducing or waiving the 30-day delay in effective date under the provisions described previously to the extent that the delay in effective date would also harm ACOs or thwart the purpose of this provision by delaying our timely administration of the Shared Savings Program functions as described in section III.A of the proposed rule (89 FR 55176). We noted that this waiver would be in part for the same reasons that we reduced the comment period on the proposed rule from 60 days to 30 days, as described in section III.A. of the proposed rule. We requested comment on this approach, including a possible finding of good cause and how ACOs would be impacted by the delay.

The following is a summary of the comments we received and our responses.

Comment: One commenter expressly supported an exception to the 30-day delay in effective date, while several other commenters urged CMS to finalize the proposed rule ''as expeditiously as it can within its legal authority'' and

[22] See *https://www.cms.gov/priorities/innovation/innovation-models/aco-primary-care-flex-model.*

others urged CMS to finalize its proposals as quickly as possible to minimize delays in shared savings distribution.

Response: We thank commenters for their support of measures to finalize changes to Shared Savings Program regulations expeditiously to reduce delays to Shared Savings Program operations.

We find that the application of the 30-day period would be impracticable and contrary to the public interest. In conjunction with our application of this rule retroactively and the reduction of the proposed rule's comment period to 30 days, we have determined that, for us to timely adjudicate applicant ACOs' eligibility to participate under the advance investment payment option and the ACO PC Flex Model for agreement periods beginning on January 1, 2025, and timely finalize repayment mechanisms necessary for ACOs to participate in two-sided models for PY 2025, we must use expenditure and revenue calculations for CY 2023, adjusted to exclude all Medicare Parts A and B payment amounts on DMEPOS claims associated with HCPCS codes A4352 and A4353, to make certain initial determinations on ACO eligibility and determine final repayment mechanism amounts, and provide related information to ACOs no later than October 17, 2024.[23] Delaying the effective date of this final rule beyond this date would harm ACOs and ACO professionals, and thwart the purpose of the rule. Were we to issue initial determinations for the advance investment payment option and ACO PC Flex Model, as well as determine final repayment mechanism amounts after this date, the aforementioned processes would not be complete, which would jeopardize entry by ACOs into new agreement periods beginning on January 1, 2025 and continued participation by ACOs in the Shared Savings Program for the PY beginning on January 1, 2025. Delaying the start of the PY 2025 would cause the harm to ACOs, ACO professionals, and CMS described in section III.A. of this final rule. Therefore, we find that there is good cause to reduce the 30-day delay in effective date for this final rule to 20 days from date of display, which provides CMS ample time to issue Phase 1 application dispositions on or before October 17, 2024 after this rule becomes effective.

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 any requirements and burden estimates under this section of the preamble. Please refer to section V. (Regulatory Impact Statement) of this final rule for a discussion of the impacts associated with the changes described in section II. (Provisions of the Regulations) of this preamble.

V. 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), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select 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) of Executive Order 12866 (Regulatory Planning and Review). A Regulatory Impact Analysis (RIA) must be prepared for rules that are significant under section 3(f)(1) of Executive Order 12866. 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 threshold. OMB's Office of Information and Regulatory Affairs has determined that this final rule does not meet the criteria set forth in 5 U.S.C. 804(2).

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. As explained elsewhere in this section, while this final rule will help preserve the accuracy of shared savings and losses calculations for ACOs in the Shared Savings Program, the great majority of ACOs will experience at most a minimal impact on their PY 2023 financial outcome. We did not prepare an analysis for the RFA because we determined, and the Secretary certified, that this final rule will 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. As previously mentioned in this section of this final rule, all but a small fraction of ACOs will experience relatively minimal changes in their PY 2023 financial outcome. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this final rule will 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 imposes no mandates on State, local, or tribal governments or on the private sector.

[23] 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* (specifying Phase 1 Dispositions to be issued on Oct. 17, 2024, at which time CMS makes available ACO Participant List and SNF Affiliate List dispositions, Beneficiary assignment eligibility Phase 1, and AIP eligibility final disposition). *See also,* CMS, Center for Medicare & Medicaid Innovation, ACO Primary Care Flex Model, Request for Applications (05/30/2024), available at *https://www.cms.gov/files/document/aco-pc-flex-rfa.pdf* (explaining that an applicant ACO will be notified whether CMS has selected them for participation in the ACO PC Flex Model during the phase 1 final disposition on October 17, 2024, which aligns with the Shared Savings Program phase 1 final dispositions).

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 final rule, we discuss the reasons that excluding payment amounts incurred in 2023 for two urinary catheter HCPCS codes [24] 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.

Preliminary estimates of PY 2023 performance after removing the specified codes, using three months of claims runout, and applying risk adjustment were used to update the impacts estimated for ACO shared savings and losses. These data were analyzed to estimate the marginal impact that catheter spending had on each ACO's performance. These marginal impact estimates continue to rely on analysis performed on preliminary data without final beneficiary assignment information and without 3 months of claims runout. Despite these remaining limitations, the precision in this analysis has increased relative to the analysis included in the proposed rule.

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 did 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 56 percent of ACOs, within +/–0.10 percent for 74 percent of ACOs, and within 0.15 percent for 83 percent of ACOs. However, the impacts would potentially be substantial at the tails of the distribution. Table 1 shows that failing to exclude the specified codes would increase the net earnings for one ACO in the study by an amount equivalent to 1.5 percent of benchmark spending relative to the policy we are finalizing to exclude the codes. At the other extreme, leaving in the specified codes was estimated to reduce earnings to another ACO by an amount equivalent to 2.4 percent of benchmark relative to the policy we are finalizing 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.

[24] 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*).

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%	-2.4%
Percentiles	5th	-0.7%	-0.4%
	10th	-0.3%	-0.1%
	20th	-0.1%	0.0%
	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	1.1%	1.5%

While providing a valid illustration of the impacts likely across the distribution of ACOs, a key component of the simulation relies on preliminary data for PY 2023 with less than 7 days of claims runout (specifically, the estimated marginal impact of catheter spending on each ACO's performance relative to benchmark) versus the 90 day claims runout used in financial reconciliation. 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 the marginal impact of catheter spending on ACO gross savings (expressed on percent of benchmark basis) would vary relative to data used in the analysis under a normal distribution with standard deviation equal to the higher of (a) 0.1 percentage points or (b) one-fourth of the absolute value of the marginal percentage impact estimated for the ACO using preliminary data, the impact of removing spending in the specified codes across all ACOs combined was estimated to be roughly budget neutral on average, ranging from a $10 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 new policy described in this final 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 policy furthers the goals of quality and efficiency by protecting the validity and integrity of the program's incentive for quality and efficiency. The provisions of this final rule, together with all existing program policies (including but not limited to those requiring authority granted in section 1899(i)(3) of the Act), result 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 changes in the CY 2024 PFS final rule were estimated to lower net spending by $330 million over the 10-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 changes in this final rule are estimated to be budget neutral for the 2023 performance year, with a range

of uncertainty spanning $10 million lower spending at the 10th percentile to $20 million higher spending at the 90th percentile. The cumulative impact of all policies including the provisions in this final 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 estimated that the implementation of the provision made in this final 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 will 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 final 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 September 23, 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 amends 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.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–22054 Filed 9–24–24; 4:15 pm]

BILLING CODE 4120–01–P

GENERAL SERVICES ADMINISTRATION

48 CFR Part 552

[GSAR–TA–2024–01; Docket No. GSA–GSAR–2024–0018; Sequence No. 1]

General Services Administration Acquisition Regulation; Technical Amendments

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Final rule.

SUMMARY: The General Services Administration (GSA) is issuing this final rule to amend the General Services Administration Acquisition Regulation (GSAR) to make needed editorial changes.

DATES: Effective: September 27, 2024.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas O'Linn, Procurement Analyst, at 202–445–0390 for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755 or *GSARegsec@gsa.gov.* Please cite GSAR–TA–2024–01.

SUPPLEMENTARY INFORMATION: This final rule amends the General Services Administration Acquisition Regulation (GSAR) to make needed technical amendments to update erroneous clause dates.

List of Subjects in 48 CFR Part 552

Government procurement.

Jeffrey A. Koses

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy, General Services Administration.

Therefore, GSA amends 48 CFR part 552 as set forth below:

PART 552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 1. The authority citation for 48 CFR part 552 continues to read as follows:

Authority: 40 U.S.C. 121(c).

552.219–18 [Amended]

■ 2. Amend section 552.219–18 by removing from the date of the clause "(DATE)" and adding "(MAY 2024)" in its place.

552.238–115 [Amended]

■ 3. Amend section 552.238–115 by removing from the date of the clause "(AUG 24)" and adding "(SEP 2024)" in its place.

552.238–120 [Amended]

■ 4. Amend section 552.238–120 by removing from the date of the clause "(AUG 24)" and adding "(SEP 2024)" in its place.

[FR Doc. 2024–22158 Filed 9–26–24; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 231127–0277]

RTID 0648–XE316

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; 2024 Commercial Closure for Snowy Grouper in the South Atlantic

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements an accountability measure (AM) for the commercial harvest of snowy grouper in South Atlantic Federal waters. NMFS projects commercial landings of snowy grouper will reach the commercial quota for the July through December season. Therefore, NMFS closes Federal waters in the South Atlantic for the commercial harvest of snowy grouper to protect the resource.

DATES: This temporary rule is effective from September 29, 2024, through December 31, 2024.

FOR FURTHER INFORMATION CONTACT: Rick Devictor, NMFS Southeast Regional Office, phone: 727–204–5518, email: *rick.devictor@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South Atlantic includes snowy grouper and is managed under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). The FMP was prepared by the South Atlantic Fishery Management Council and NMFS, and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622. All weights described in this temporary rule are in gutted weight.

The commercial annual catch limit (ACL) for snowy grouper in 2024 is 106,174 pounds (lb) or 48,160 kilograms (kg). The commercial ACL is divided into two commercial quotas, with a separate quota for each 6-month fishing season. Seventy percent of the commercial ACL is allocated for the January through June commercial fishing season and that quota is 74,322 lb (33,712 kg) for 2024. The remaining 30 percent of the commercial ACL for the July through December fishing season is a quota of 31,852 lb (14,448 kg) for 2024 [50 CFR 622.190(a)(1)(i)(B) and (ii)(B)]. Any commercial quota remaining from the first season is added to the commercial quota in second season, but any commercial quota remaining from the second season is not carried forward into the next fishing year. The January through June quota was projected to be reached on June 4, 2024, and commercial harvest was closed (89 FR 47871, June 4, 2024). Subsequently, updated commercial harvest information showed that 8,035 lb (3,645 kg) of that quota was not harvested, and it was added to the 2024 commercial quota for the July through December season.

Under 50 CFR 622.193(b)(1), NMFS is required to close the commercial sector for snowy grouper when the commercial quota specified in 50 CFR 622.190(a)(1) is reached or is projected to be reached. NMFS projects that commercial landings of snowy grouper will reach the commercial quota for the 2024 July