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CMS Proposes Significant Changes to the Medicare Shared Savings Program and 60-Day Rule

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Under the CY 2025 Medicare Physician Fee Schedule (PFS) proposed rule, CMS proposes several modifications to the Medicare Shared Savings Program (MSSP) that would become effective in performance year 2025. CMS also proposed finalizing certain amendments to the existing regulations for Medicare Parts A, B, C, and D regarding the standard for reporting and returning identified overpayments under the 60-day rule.

Below, we summarize the key proposed changes to the MSSP and the 60-day rule and discuss their potential implications. Comments on the Proposed Rule are due on September 9, 2024.

Proposed Changes to the MSSP

As an overview, the proposed changes to the MSSP include:

Requiring Accountable Care Organizations (ACOs) to report the APM Performance Pathway (APP) Plus quality measure set;

Establishing a new "prepaid shared savings" option to assist eligible ACOs with a history of earning shared savings;

Implementing a health equity benchmark applicable to ACOs in agreement periods beginning on January 1, 2025, and in subsequent years (informed by the ACO REACH Model);

Implementing additional protections against Significant, Anomalous, and Highly Suspect (SAHS) billing activity;

Establishing a calculation methodology to account for and other processes to address improper payments; and

Seek comment on establishing a higher risk/reward option than the current ENHANCED track.

APP Plus Quality Measure Set

The APP Plus quality measure set is aligned with the ten Adult Universal Foundation measures that have been established by CMS to streamline quality measures across CMS quality programs. As established by the 2024 Physician Fee Schedule final rule, five of these ten measures were already incorporated in the existing APP quality measure set, which would no longer be utilized if this rule is finalized as proposed. The proposed implementation of the new APP Plus quality measure set would entail an incremental phase-in of the additional

five measures on top of those measures in the APP quality measure set. Additionally, if finalized, ACOs would not be able to report data under the original Merit-based Incentive Payment System (MIPS) MIPS Clinical Quality Measures (CQMs) collection type as CMS seeks to transition to a focus on the Electronic Clinical Quality Measures (eCQM) and Medicare CQM collection types under the APP Plus quality measure set.

This proposed change is intended to improve alignment across CMS programs and to encourage ACOs to adopt digital quality measurements. CMS believes that adoption of digital quality measurements will ultimately reduce the burden on ACOs by making data collection, sharing, and reviewing more efficient.

Prepaid Sharing Savings

Expanding on the advance investment payments (AIP) established by the 2023 Medicare Physician Fee Schedule final rule and building on research by the CMS Innovation Center, CMS also now proposes to offer prepaid shared savings to certain ACOs with a history of earning shared savings. The purpose of the prepaid shared savings is to allow participants to make investments in direct beneficiary services and improve care coordination through staffing and health care infrastructure. At least 50 percent of prepaid shared savings would be reserved to be spent on direct beneficiary services not directly reimbursed by Traditional Medicare, such as meals, dental, vision, hearing, and Part B cost-sharing support. The remaining 50% would be used for staffing and health care infrastructure. If finalized, CMS anticipates issuing sub-regulatory guidance on the appropriate use of funds for direct beneficiary services. Notably, if the rulemaking if finalized, CMS will make a determination that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives, 42 CFR § 1001.952(ii)(2), is available to protect direct beneficiary services that are made in compliance with this new proposed policy. If finalized, this will allow for greater flexibility regarding the items and services that may be provided directly to beneficiaries in furtherance of improving overall health.

To the extent the ACO does not actually earn these savings in a particular year, CMS would be able to withhold or terminate the ACO's prepaid shared savings. In order to be eligible for the payments, an ACO would have to meet the following requirements (with further detail set forth in the proposed rule):

- The ACO must be a renewing ACO;
- The ACO must have received a shared savings payment for the most recent performance year;
- The ACO must have a positive prior savings adjustment;
- The ACO must not have any outstanding shared losses or advance investment payments that have not yet been repaid to CMS after reconciliation for the most recent performance year for which CMS completed financial reconciliation;
- If the ACO received prepaid shared savings in the current agreement period or a prior agreement period, the ACO must have fully repaid the amount of prepaid shared savings received;
- The ACO must be participating in Levels C-E of the BASIC track or the ENHANCED track;
- The ACO must have in place an adequate repayment mechanism; and
- During the agreement period immediately preceding the agreement period in which the ACO would receive prepaid shared savings, the ACO must have:
  - Met the quality performance standard as specified under § 425.512; and

- Not been determined by CMS to have avoided at-risk beneficiaries.

CMS hopes that these prepaid sharing savings payments would allow ACOs to invest in staffing, health care infrastructure, and direct beneficiary services in a manner that ultimately improves the quality and efficiency of beneficiary care.

Health Equity Benchmark

CMS proposes to provide an upward adjustment to an ACO's historical benchmark based on the proportion of beneficiaries they serve who are dually eligible or enrolled in the Medicare Part D low-income subsidy (LIS). This Health Equity Benchmark Adjustment (HEBA) would hopefully serve to encourage ACOs to serve more beneficiaries that fall into these categories and build on existing Shared Savings Program policies finalized in the CY 2023 and CY 2024 PFS final rules. These policies aim to advance health equity including the establishment of health equity adjustment to an ACO's MIPS quality performance score. CMS hopes that in tandem with the proposed prepaid shared savings payment, the HEBA will encourage resolution of the unmet health-related social needs of the beneficiaries that ACOs serve in rural and underserved communities. The HEBA would include a potentially higher benchmark and make it more likely for an ACO serving rural and underserved communities to earn shared savings and reduce barriers, such as high start-up costs, to forming ACOs in order to serve those populations. The proposed HEBA would offer a third method of upwardly adjusting an ACO's historical benchmark, in addition to the existing regional adjustment and prior savings adjustment. If finalized, the HEBA would be available beginning January 1, 2025, and every year thereafter. Notably, ACO REACH already includes a HEBA.

Addressing SAHS Billing Activity

In order to address SAHS billing activity in a consistent manner, CMS proposes to create a formal policy detailing how associated adjustments will be made to the financial calculations for the MSSP. Specifically, CMS proposes that it should have the sole discretion to identify cases of SAHS billing activity warranting adjustments and the associated codes. Under the proposed rule, CMS provides several example criteria it would use to determine whether a particular code should be removed from the financial calculations for the MSSP, including whether the claims in question may be disproportionately represented by Medicare providers or suppliers whose Medicare enrollment status has been revoked. The concern regarding highly suspect billing activity arose due to concerns raised by ACOs and other interested parties regarding an increase in Medicare billing for selected intermittent urinary catheter supplies on DMEPOS claims in CY 2023 – alleging that the increase in payments represents fraudulent activity. Under current regulations, there is no method for CMS to address the effect of SAHS billing activity on financial calculations for the MSSP. With this proposed change, CMS hopes to improve accountability under and integrity of the MSSP.

Impact of Improper Payments

Under the Proposed Rule, CMS seeks to implement new policies to address the program's interactions with payments determined to be improper. These policies address: (i) the calculation methodology used to account for the impact of improper payments in recalculating expenditures and payment amounts; and (ii) the adjustment to the historical benchmark used to account for the impact of improper payments. In the Proposed Rule, CMS identified different factors that it may consider in its decision to reopen an initial determination of an ACO's financial performance pursuant to § 425.315(a)(1)(i) or (ii,) to account for the impact of improper payments that affect the determination of whether an ACO is eligible for shared savings or liable for shared losses, and the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO.

Medicare Parts A and B Overpayment Provisions of the Affordable Care Act

Acknowledging the lack of finalization of proposals made in a December 2022 Proposed Rule (December 2022 Overpayment Proposed Rule) and in response to certain comments to that proposed rule, CMS put forward new proposals to amend the regulatory section that addresses reporting and returning of overpayments for Medicare Parts A and B, as well as Parts C and D (the 60-day rule). As we discussed in a prior article, the December 2022 Overpayment Proposed Rule proposed to amend the existing regulations regarding the standard for an "identified overpayment" to align with the statutory language in section 1128J(d)(4)(A) of the Social Security Act. If finalized, the proposed changes would assign the meaning of the terms "knowing" and "knowingly" in the False Claims Act at 31 U.S.C. 3729(b)(1)(A) to the regulations for purposes of triggering the requirement for return of Medicare overpayments. Specifically, CMS proposes to remove the existing "reasonable diligence" standard and adopt by reference the False Claims Act definition of "knowing" and "knowingly" as set forth at 31 U.S.C. 3729(b)(1)(A) as the new standard, which would require that the provider or supplier have actual knowledge of the existence of the overpayment, or act in reckless disregard or deliberate ignorance of the overpayment.

In addition, CMS proposes adding new 42 CFR § 401.305(b)(3) which would provide for circumstances under which the deadline for reporting and returning overpayments could be suspended to allow time for providers and suppliers to investigate and calculate overpayments. Proposed § 401.305(b)(3) would suspend the deadline to report and return an overpayment if:

(1) a person has identified an overpayment but has not yet completed a good-faith investigation to determine the existence of related overpayments that may arise from the same or similar cause or reason as the initially identified overpayment; and

(2) the person conducts a timely, good-faith investigation to determine whether related overpayments exist.

If these conditions are met, the deadline for reporting and returning the initially identified overpayment and related overpayments that arise from the same or similar cause or reason will remain suspended until the *earlier* of: (i) the date that the investigation of related overpayments has concluded and the aggregate amount of the initially identified overpayments and related overpayments is calculated; or (ii) the date that is 180 days after the date on which the initial identified overpayment was identified. If the person does NOT conduct an investigation, or the investigation is not timely or not conducted in good faith, the identified overpayment must be reported and returned by day 60. If the person does conduct a timely, good faith investigation, suspension of the report and return obligation under § 401.305(b)(3) begins on day 1. The suspension ends when the investigation is concluded and the initially identified overpayment and related overpayments, if any, are calculated, or by day 180, whichever is earlier. The overpayment must be reported and returned within 60 days after either completion of the investigation or day 180, whichever is earlier.

These proposals codify the six (6) month investigation window previously understood to exist under CMS commentary to the 60-day rule, in response to comments received for the December 2022 Overpayment Proposed Rule. However, it is unclear how this new provision impacts prior CMS commentary stating that a provider or supplier could take more time to investigate when there are "extraordinary circumstances." CMS previously stated in preamble guidance that extraordinary circumstances "may include unusually complex investigations that the provider or supplier reasonably anticipates will require more than six months to investigate, such as physician self-referral law violations that are referred to the CMS Voluntary Self-Referral Disclosure Protocol (SRDP)." While not expressly discussed in the current proposal, this flexibility does not seem to align with the 180-day standard proposed.

Those affected by this rule change should consider submitting written comments to CMS before the September 9, 2024, 5:00 p.m. deadline. Should these proposals be finalized, providers and suppliers will need to review their overpayment identification and return policies to incorporate the updated standards.

If you have any questions about this alert, please reach out to one of the authors or a member of the Health Law group with whom you regularly work.