August 30, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1807–P

Submitted electronically to: http://www.regulations.gov

Re: Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments (CMS–1807–P)

Dear Administrator Brooks-LaSure:

Premier Inc. appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the calendar year (CY) 2025 Physician Fee Schedule (PFS) proposed rule, which was published in the July 31, 2024 *Federal Register*.

In our detailed comments below, Premier urges CMS to:

- Establish a more adequate transition to the new Medicare Shared Savings Program (MSSP) quality reporting requirements, including ensuring requirements are consistent with CMS' digital quality measurement strategy, not adding more measures to the MSSP quality measure set and piloting requirements prior to broad adoption;
- Modify the proposed prepaid shared savings option to allow accountable care organizations (ACOs) to utilize funds for additional activities and reduce reporting requirements;
- Modify the proposed health equity adjustment to ensure more ACOs and underserved communities may benefit from the policy;
- Finalize proposals to establish process for addressing the impact of significant, anomalous, and highly suspect billing activities on MSSP ACOs and continue to work with ACOs to improve the process for reporting suspected fraud, waste and abuse;
- Establish a higher risk option within MSSP while maintaining the existing ENHANCED Track;
- Finalize changes to follow-up beneficiary notification requirements and consider additional changes to the notification process and other flexibilities to allow ACOs to better engage with beneficiaries in meaningful ways;
- Repeal the new certified EHR technology (CEHRT) requirements for ACOs;
- Eliminate the arbitrary high-low revenue distinction in MSSP;
- Finalize proposal to allow use of audio-only technology for telehealth services under certain circumstances;
- Finalize proposal to align implementation date for Electronic Prescribing of Controlled Substances (EPCS) Program for long-term care prescribers with timeline for updating the NCPDP SCRIPT standards.

I. BACKGROUND ON PREMIER INC.

Premier is a leading healthcare improvement company and national supply chain leader, uniting an alliance of 4,350 hospitals and approximately 325,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier's sophisticated technology systems contain robust data gleaned from nearly half of U.S. hospital discharges, 812 million hospital outpatient and clinic encounters, and 131 million physician office visits. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,460 manufacturers to source the highest quality and most cost-effective products and services. Premier's work is closely aligned with healthcare providers, who drive the product and service contracting decisions using a data driven approach to remove biases in product sourcing and contracting and assure access to the highest quality products. Premier runs the largest population health collaborative in the country, the Population Health Management Collaborative, which is comprised of over 70 ACOs.

A Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government and other entities to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare.

II. MEDICARE SHARED SAVINGS PROGRAM (MSSP)

QUALITY PERFORMANCE STANDARD AND REPORTING REQUIREMENTS

Background and Proposals

The MSSP's quality performance standard is used to determine whether an ACO is eligible to receive shared savings for a performance year. Over the last couple of years, CMS has finalized several fundamental changes to the MSSP quality performance standard, including sunsetting the Web Interface reporting mechanism in performance year (PY) 2025 and requiring ACOs to report electronic clinical quality measures (eCQMs) or MIPS clinical quality measures (CQMs) under the new Alternative Payment Model (APM) Performance Pathway (APP). As part of last year's rulemaking, CMS established a new temporary collection type – Medicare CQMs – to aid ACOs with the transition to eCQM / MIPS CQM reporting under the APP.

Additionally, in Spring 2023, CMS released its vision for an aligned quality measure set across Medicare quality reporting programs, known as the Universal Foundation. Currently, five of the six measures in the APP are included in the Adult Universal Foundation measure set. CMS proposes to establish the APP Plus measure set, which will incrementally increase the number of APP measures to include the remaining measures under the Adult Universal Foundation measure set. Under this proposal, CMS would adopt the existing APP quality measures plus five newly proposed measures over the course of four years. The APP Plus measure would include the following measures:

- For PY 2025, eight measures (five eCQMs/Medicare CQMs, two administrative claims measures, and the CAHPS for MIPS survey measure)

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

While the APP Plus measure set would be an optional set for APP reporters, CMS proposes to require MSSP ACOs to report the APP Plus quality measure set. CMS also proposes that beginning in PY 2025, eCQMs and Medicare CQMs would be the only collection type available for MSSP ACOs, essentially sunsetting the MIPS CQM as a collection type for MSSP ACOs.

Finally, CMS proposes to extend the eCQM reporting incentives for PY 2025 and subsequent years. Under the policy, ACOs would meet the quality performance standard if the ACO:

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

Premier's Recommendations

While Premier has long advocated for allowing ACOs to report measures through reporting mechanisms other than the Web Interface and reducing the number of required measures, Premier has continued to voice concern that the new APP reporting policy places significant burden and costs on ACOs during a time when providers already face significant financial pressures. As discussed in greater detail below, ***Premier continues to strongly urge CMS to work with stakeholders to align the new reporting requirements with CMS' broader digital quality measurement strategy and provide ACOs with additional time to transition to the APP reporting requirement prior to sunsetting the Web Interface.***

Additionally, while Premier is supportive of aligning measures across quality programs under the Universal Foundation, ***Premier strongly urges CMS to not modify the APP measure set at this time***. As previously noted, ACOs face a number of operational challenges with implementing eCQMs under the new APP reporting requirements. Modifying the measure set at this time will only serve to increase the level of burden and complexity that ACOs face in adopting these new changes to meet the PY 2025 implementation deadline.

Premier is also deeply concerned by CMS' proposal to eliminate the MIPS CQMs as a reporting option for ACOs. Many MSSP ACOs have invested both time and resources in implementing this reporting option to meet the APP reporting requirements in time for the PY 2025 deadline. CMS did not previously indicate it planned to remove this as an option. Discontinuing this option will not only result in many ACOs having wasted valuable time and resources, it will also require these ACOs to quickly pivot to another option over the course of only a few months if this policy is finalized. ***Premier strongly urges CMS to maintain MIPS CQMs as a reporting option for ACOs.***

Finally, ***Premier continues to urge CMS to work with stakeholders to develop the ideal measure set for ACOs.*** As discussed in greater detail below, quality measurement for ACOs should recognize the unique role that ACOs play in coordinating care across the continuum. As a result, ***Premier urges CMS to explore adopting best practices from how quality reporting is conducted by health plans.***

Overall, ***Premier continues to have significant concerns with CMS' plan to sunset the Web Interface and require all ACOs to report the APP through either eCQMs or Medicare CQMs***, beginning in PY 2025. As we have highlighted previously in comments to CMS, ACOs continue to face numerous challenges with transitioning to these reporting requirements. Failure to recognize and address these challenges will result in ACOs not only removing participants from their ACO but also dropping from the MSSP completely – ultimately jeopardizing the Administration's goal of aligning all Medicare beneficiaries in an accountable care relationship by 2030. ***Premier urges CMS to:***

- **Consider the current limitations of electronic health records (EHRs) and burden associated with eCQM reporting.** To report eCQMs, ACOs will be required to aggregate data across multiple tax identification numbers (TINs) and EHR systems. It is critically important to understand that ***ACOs vary widely in their electronic data extraction and aggregation capabilities.*** Some ACOs have a single EHR that covers the entire organization, but more commonly ACOs have multiple different EHR instances across the organization – in some cases, numbering well over 100 different EHR instances. For ACOs with multiple EHRs, producing eCQMs from those disparate systems requires significant investment in time, money and effort in changing workflows and acquiring new technology services, all of which would be better served focusing on patient care.

  Additionally, ***certified EHR technology (CEHRT) standards have not advanced enough to support quality measurement derived from multiple sources.*** The interoperability standards aim to ease data sharing across providers; however, these standards are still under development and evolving. As a result, aspects of the ACO quality policies are not feasible in current systems. For example, CEHRT only allows for reporting eCQMs from a single EHR. As a result, combining data from multiple EHRs to produce a single result is not a capability that most ACOs have. Similarly, CMS requires that ACOs submit deduplicated patient data. No other entity that participates in CMS quality programs is required to complete this level of aggregation and reporting.

  CMS recently released an open source dedupliFHIR tool to assist ACOs in data aggregation and patient matching. As with any new technology or tool, its first iteration is not comprehensive and will require refinements. Specifically, CMS should allow time for this tool to be tested with real world data to understand whether its use can be replicated across ACOs with similar results and with what degree of accuracy. In addition, the tool should be designed to normalize the data, perform phonetic matching and accurately handle multiple data elements, such as multiple addresses for one patient. While tools like dedupliFHIR will assist in these efforts, it does not address all the concerns and should undergo further testing.

- **Recognize ACOs are fundamentally different than clinicians and groups.** The new reporting requirements will also essentially align the MSSP quality standard with MIPS. This is a fundamentally flawed approach. ACOs reflect coordination of care across the continuum, as compared to MIPS, which reflect point-in-time encounters by individual clinicians and groups. ACOs are a network of aligned providers rather than a specific provider type. While Premier generally supports alignment across CMS programs, the current policies set MIPS as the gold standard, with APMs as the entity that must align with MIPS. This is antithetical to the goal of moving clinicians from volume to value. Rather, ***CMS should create the ideal measurement approach for APMs and align setting-specific and provider-specific measurement approaches so that providers are encouraged to move to APMs.*** Requiring ACOs to report all-payer data is comparable to requiring health plans to report on other payers' populations. Instead of building ACO quality reporting based on the structure used for individual clinicians***, Premier strongly urges CMS to***

look to how quality reporting is conducted by health plans. For example, CMS should explore adopting a similar framework to digital HEDIS, which combines data from multiple sources, including EHRs, clinical registries or health information exchanges (HIEs), case management systems and claims data.

Another significant change to the reporting requirements is that CMS will now require ACOs that report eCQMs to report on all patients who meet the measure specifications, rather than just Medicare beneficiaries aligned to the ACO. Premier understands CMS' intent is to assess the quality of care across all patients and all payers, similar to the approach CMS uses in other quality reporting programs. All-payer measurement is ideal for setting provider-specific measurement as you are holding providers accountable for their entire patient population. ACOs are held accountable for cost for a defined patient population by partnering with providers to innovate and coordinate care. ACOs themselves do not directly provide care. Moreover, the ACO entity does not have the ability or flexibilities to design care interventions for other payers' patients. The ACO also lacks access to data on patients outside the ACO entity, which can further complicate the ability of the ACO to coordinate care effectively. Requiring ACOs to report on the all-payer population of its participant providers is comparable to requiring a health plan to report on other payers' populations.

- **Consider the unintended consequences of quality policies.** In 2021, CMS set a goal of getting all fee-for-service Medicare beneficiaries into a care relationship that is accountable for quality and total cost of care by 2030. CMS followed up on this goal by releasing a strategy for increasing specialist engagement and integration into value-based care models, such as MSSP. Given the challenges associated with the new APP-based quality reporting requirements, some ACOs are considering narrowing their participants list, including removing specialists. This will ultimately hinder CMS' ability to align all beneficiaries with ACOs and increase specialist engagement. For example, the move to all-payer data quality measurement will now include the total population of patients seen by all providers affiliated with the ACO, including specialists. All-payer measurement could significantly impact ACO performance on certain measures where historically certain ACO clinicians have not performed these assessments or measurements because they are not relevant to or reflective of the clinical care the clinician is furnishing. For example, most orthopedists or ophthalmologists do not screen patients for depression. However, all-payer APP-based quality reporting could cause their patients to be included in the denominator of this measure and adversely affect the ACO's measure performance score. As a result, some ACOs are considering removing specialists from their ACO. Additionally, some smaller or independent physician practices would need to make significant investments in their EHR systems to successfully report eCQMs under the new requirements. As practices consider the business case for this investment, some are likely to determine that continuing to partner with an ACO is no longer feasible.

While Premier appreciated CMS adding the additional reporting option of Medicare CQMs as part of last year's rulemaking, CMS has indicated that Medicare CQMs will only be a temporary reporting option for ACOs and that ultimately ACOs are expected to transition to eCQM reporting. Medicare CQM reporting still requires significant investment by ACOs. Without clear guidance from CMS on how long Medicare CQMs will be available, many ACOs are hesitant to invest the time and resources into this reporting option. As a result, ***Premier urges CMS to make Medicare CQMs a permanent reporting option and only propose its removal once digital quality measurement (dQM) reporting is achieved by all ACOs.*** Additionally, CMS must recognize that Medicare CQMs only partially address some of the challenges that ACOs face with reporting. Vendors are still trying to operationalize Medicare CQM reporting, as the first Medicare CQM patient list was not shared until this past May. Some vendors have elected to not support this option and other EHR vendors will not be ready to do so until late 2025.

Digital quality measurement is the goal, but an adequate transition is needed. CMS has continued to articulate its goal of moving to full digital measurement, with the goal of streamlining CMS' approach to data collection, calculation and reporting to fully leverage clinical and patient-centered information for measurement, improvement and learning. Premier appreciates CMS' commitment to advancing digital measurement as we have long been committed to advancing providers' capability to analyze data from multiple sources and to manage the health of their populations.

Premier believes ACOs can be the leaders in advancing digital quality measurement, as ACOs are inherently incented to collect data across the care continuum for their beneficiaries. ACO quality measurement represents an opportunity to understand how we can use existing and novel data sources to accurately assess care across the continuum.

With the transition to these new reporting requirements, the MSSP quality reporting standard would be the only pay-for-performance program that requires reporting of an eCQM measure set. For the past several years, CMS has gradually increased the number of eCQMs available across all quality reporting programs. However, in recognition of the challenges associated with reporting eCQMs, CMS has provided notable flexibility in these programs, such as allowing clinicians to select their measures (as under MIPS) or limiting the measures to pay-for-reporting programs. ***It is unreasonable to place a more stringent reporting approach on ACOs, that must combine data across settings, while setting-specific quality programs are provided with additional flexibility.***

As noted above, adapting workflows, data capture and other operational strategies necessary to monitor and report measures under these new requirements will take time and significant resources. As a result, ***Premier strongly urges CMS to adopt the following changes to ensure a more gradual transition to the new reporting requirements:***

- ***Avoid requiring ACOs to report additional measures under the APP Plus measure set at this time.*** At a minimum, CMS should provide ACOs with the option of reporting either the original APP measure set or the APP Plus measure set.
- ***Align with CMS digital quality measurement strategy.*** Over the last couple of years, CMS has sought input on its transition to dQM. As part of this, CMS has noted that it is considering how eCQMs "can be refined or repackaged to fit within the potential future dQM definition," noting that "limitations in data standards, requirements, and technology have limited their interoperability." Given these challenges, ***Premier strongly urges CMS to assess the new MSSP quality reporting requirements as part of its broader enterprise-wide dQM initiative***. As noted above, the transition to the new reporting requirements will require significant time and resources from ACOs. As a result, Premier is concerned that eCQM reporting requirements could shift midstream as CMS continues to evaluate its broader dQM strategy and impose even more burden and instability on ACOs. At a minimum, CMS should articulate how the ACO eCQM reporting requirements fit into CMS' broader goals around dQM, given the limitations around eCQMs already acknowledged by CMS.
- ***Adopt Medicare CQMs as a permanent reporting option.*** As noted above, ACOs are hesitant to invest in Medicare CQMs since CMS has indicated when it will ultimately sunset the option in the future. As a result, ***Premier urges CMS to adopt Medicare CQMs as a permanent reporting option and propose to sunset the option only when ACOs are successfully able to report dQMs.*** At a minimum, CMS should provide ACOs with at least three years notice prior to proposing to sunset Medicare CQMs as a reporting option.

- ***Pilot reporting requirements first.*** Given the numerous technical barriers to eCQM and Medicare CQM reporting highlighted above, ***Premier strongly recommends that CMS recruit ACOs to pilot various approaches.*** This would be an opportunity for CMS to evaluate and address many of these technical challenges and to adapt its dQM requirements prior to requiring broad adoption. This would also be an opportunity to further evolve the requirements beyond eCQMs to better fit with CMS' goals for digital quality measurement. One of the goals of CMS' dQM strategy is to provide clinicians with real-time feedback, which is not currently feasible through eCQMs. The pilot would also be an opportunity for CMS to explore and develop necessary risk adjustment methodologies, exclusion criteria and patient stratification. ***At a minimum, Premier urges CMS to delay sunsetting the Web-Interface and MIPS CQM reporting methods for three additional years to allow time for ACOs to adapt to the new requirements and test available tools.***

OPTION OF PREPAID SHARED SAVINGS

Background and Proposals

During 2023 rulemaking, CMS established an opportunity for certain low-revenue ACOs entering agreement periods after Jan. 1, 2024 to receive upfront shared savings, known as Advance Investment Payments (AIP). Under the policy, AIP can be used for the following categories: increased staffing, healthcare infrastructure, and the provision of accountable care for underserved beneficiaries, which may include addressing social determinants of health (SDOH). Many stakeholders, including Premier, had encouraged CMS to expand the policy to include high-revenue ACOs and ACOs already participating in the program. CMS acknowledges that it believes all ACOs could benefit from investments in staffing, healthcare infrastructure and care for underserved populations; however, it believes it is too premature to expand the AIP at this time. Instead, CMS proposes to establish a prepaid shared savings option for certain ACOs with a history of earning shared savings while participating in MSSP. To be eligible, ACOs would need to meet the following criteria:

- Entering a new agreement period beginning on or after Jan. 1, 2026;
- Received a shared savings payment for the most recent performance year occurring prior to the new agreement period and that CMS has conducted a financial reconciliation for;
- Received a positive prior savings adjustment at application disposition for the agreement period in which they would receive prepaid shared savings;
- Does not have any outstanding shared losses, AIPs or prepaid shared savings;
- Participating in Levels C-E of the BASIC track or the ENHANCED track during the agreement period in which they would receive prepaid shared savings;
- Has an adequate repayment mechanism in place that can be used to recoup outstanding prepaid shared savings; and
- Met the quality performance standard and was not determined to have avoided at-risk beneficiaries during the preceding agreement period.

Prepaid shared savings payments would be distributed on a quarterly basis and would be recouped from shared savings determined during the annual ACO financial reconciliation cycle. If the ACO does not earn sufficient shared savings to offset the advanced payment, CMS may withhold or terminate the ACO's prepaid shared savings. ACOs could request a smaller amount of prepaid shared savings than they are eligible for.

CMS plans to align the application cycle for prepaid shared savings with the MSSP application process. CMS would provide preliminary information to the applicant ACO about its eligibility to receive prepaid shared savings during the Phase 1 application cycle requests for information, and a final determination about its eligibility to receive prepaid shared savings at the time of final application dispositions.

An ACO would be required to submit a spend plan as part of its application specifying how the ACO would spend the prepaid shared savings during the first performance year, including direct beneficiary services that would be provided and investments that would be made. In addition to submitting a spend plan, ACOs would be required to publicly report the spend plan, total amount of prepaid shared savings received and an itemization of how the prepaid shared savings was spent during each performance year. CMS also plans to make this data publicly available through a public use file.

For each performance year, ACOs would be permitted to use up to 50 percent of their estimated annual prepaid shared savings on staffing and healthcare infrastructure and up to 100 percent on direct beneficiary services. In the proposed rule, CMS specifies the permitted uses for staffing, infrastructure and direct beneficiary services.

CMS proposes to recoup prepaid shared savings that ACOs are unable to fully repay through their earned shared savings. If there are insufficient shared savings to recoup the prepaid shared savings, CMS would pause paying future prepaid shared savings payments and carry forward the remaining balance owed to subsequent performance years in which the ACO achieves shared savings. If an ACO has an outstanding balance of prepaid shared savings after the calculation of shared savings or losses for the final performance year of an agreement period, the ACO must repay any outstanding amount of prepaid shared savings it received in full upon request from CMS within 90 days after receipt of the notification.

Premier's Recommendations

While Premier supports establishing a prepaid shared savings option for ACOs, we are concerned that the policy may be too restrictive in terms of the types of activities that ACOs may use the upfront payment amount for, which will ultimately limit utilization. For example, many ACOs currently use a portion of their shared savings to pay performance incentives, which are a core component of an ACO's provider engagement strategy, especially for specialists. Over the last couple years, CMS has continued to explore ways to further strengthen the engagement of specialists in value-based care models. Performance incentives are a key tool for ACOs to engage specialists. As a result, Premier encourages CMS to modify the policy to allow for additional activities, such as performance incentives.

Additionally, Premier encourages CMS to provide additional information and clarity on the ability of ACOs to reduce the total amount of shared savings that are prepaid. As with other recommendations, Premier believes increased flexibility with this proposed policy will provide greater consideration and ultimately adoption of this proposal resulting in positive downstream impacts for beneficiaries.

Finally, ***Premier encourages CMS to modify the policy to reduce the amount of documentation that ACOs must publicly report.*** As noted above, ACOs would be required to not only publicly report their spend plans and amounts of prepaid shared savings received, but would also be required to provide an itemized breakout of how savings were spent. Premier understands the interest in providing greater transparency around how prepaid shared savings are used. However, providing an itemized breakout of spending seems unnecessarily burdensome for ACOs. Premier encourages CMS to revisit this requirement. At a minimum, CMS should only require ACOs to report on aggregate spending across each category of its spend plan.

HEALTH EQUITY BENCHMARK ADJUSTMENT

Background and Proposal

Consistent with the Administration's priorities for advancing health equity, CMS proposes a health equity benchmark adjustment (HEBA), which would be an upward adjustment to the historical benchmark intended to benefit ACOs that serve a larger proportion of beneficiaries from underserved communities and that receive a lower regional adjustment and/or lower prior savings adjustments. Under the policy, which is effective for agreement periods beginning on or after Jan. 1, 2025, ACOs would receive the highest of the positive adjustments for which it is eligible – (1) regional adjustment; (2) prior savings adjustment; or (3) HEBA.

CMS proposes to calculate the HEBA as the product of the HEBA scaler and the proportion of the ACO's assigned beneficiaries who are dually eligible for Medicare and Medicaid or enrolled Medicare Part D Low-Income Subsidy (LIS). The HEBA scaler is calculated as the difference between 5 percent of national per capita Parts A and B expenditures for assignable beneficiaries and the highest of regional adjustment, prior savings adjustment or no adjustment (in cases where the regional adjustment is negative or ACO is not eligible for prior savings adjustment). ACOs with less than 20 percent of their aligned beneficiaries enrolled in LIS or dually eligible would be ineligible for a HEBA. CMS seeks comment on if it should utilize the area deprivation index (ADI) for purposes of determining eligibility for and the amount of any HEBA and related factors including the calculation of the ADI.

Premier's Recommendations

Premier supports CMS' proposal to adopt a HEBA to the MSSP, which recognizes the critical need to modify current financial methodologies to ensure benchmarks are appropriately set to account for the needs of undeserved patients. However, Premier is concerned that the policy as proposed will have minimal impact on ACOs. CMS notes in the rule that it estimates based on 2023 data that only 20 ACOs would have a HEBA greater than the other two adjustments and therefore would benefit from this policy. ***Premier urges CMS to modify the policy to remove the requirement that ACOs have at least 20 percent of their aligned beneficiaries enrolled in LIS or dually eligible,*** as this will significantly reduce the number of ACOs that qualify. ***Premier also urges CMS to explore additional methodologies that would allow more ACOs to benefit from this policy, such as applying the HEBA in addition to the other adjustments.***

Premier also encourages CMS to explore additional flexibilities and payments for ACOs to strengthen their focus on addressing health equity, such as paying for services that address SDOH. CMS should consider allowing ACOs to opt into receiving payment for enhanced services that would allow ACOs to better partner with CBOs in providing innovative wrap-around services aimed at addressing SDOH and advancing health equity. CMS has adopted similar policies in other Innovation Center models. For example, under the Oncology Care Model, participants received a monthly fee for delivering enhanced services. This allowed participants to create triage clinics, hydration stations and hire financial counselors.

Finally, ***Premier continues to encourage CMS to explore adopting additional or new data sources as they become available that are more reflective of whether a patient is considered underserved***. Dual eligible beneficiary percentages will vary across states depending on nonuniform criteria for Medicaid eligibility. Using ADI has its own challenges, as some populations that may appear underserved relative to others in their surrounding area or state, but may not be classified as underserved when compared to other communities nationwide. CMS recently announced that it will modify the health equity adjustment under the

ACO REACH model to replace the national/state blended ADI with an area-level socioeconomic deprivation measure that uses standardized variables. CMS has yet to release details on that methodology. Premier encourages CMS to work with stakeholders to explore if that new methodology would be a better metric for the proposed MSSP HEBA. Additionally, as CMS works to develop a metric, it will be critical to account for redundant social risk variables. Many of the variables used within social risk indices, such as the ADI, are highly correlated even across domains (e.g., housing and transportation, minority status, socio-economic status, etc.). This can lead to overstating certain aspects of social risk within the composite index. There are certain statistical techniques that can help account for these redundancies and ensure the variables are not double counted and ultimately improve the accuracy and fairness of the index, as was highlighted in a journal article utilizing Premier data.[1]

REOPENING ACO PAYMENT DETERMINATIONS

Background and Proposals

If CMS determines that shared savings or losses were calculated in error, it may reopen either the initial or final determination and issue a revised determination either (1) no later than four years after the initial determination of savings or losses for a relevant performance year or (2) at any time in the case of fraud or similar fault. CMS proposes several revisions to its determination process to better account for instances where improper payments are identified and to create a process by which ACOs can request a reopening.

CMS proposes modifications to regulations to make clear that CMS has sole discretion to determine whether to reopen a payment determination. CMS also seeks comment on several considerations that would inform its decision on whether to reopen a determination of an ACO's financial performance to account for improper payments. This could include identification of improper payments by the CMS Center for Program Integrity (CPI) and law enforcement agencies that are determined to potentially impact MSSP expenditures used in program calculations. Under this scenario CMS would conduct an initial analysis to determine if the improper payments had significant enough impact to warrant reopening determinations. CMS notes it is considering limits on when it might reopen determinations to strike a balance between improving accuracy of calculations and minimizing burden on ACOs and CMS. CMS also proposes the methodology by which it will recalculate expenditures to account for improper payments.

Finally, CMS proposes a process through which an ACO may request a reopening of an initial or final shared savings or losses determination. Under this proposed process, CMS specifies the types of information that an ACO must submit. Upon receiving the request, CMS would evaluate it and ask for supplemental information if needed. CMS would also work with CPI and law enforcement agencies to identify, validate and quantify improper payments potentially impacting expenditures used in program calculations, potentially contingent on the conclusion of an investigation that is underway. Finally, CMS may conduct an initial analysis to consider the basis for a reopening and the significance of the improper payments to an ACO's financial calculations. Depending on the magnitude of the improper payments or impact on ACOs, CMS may consider reopening the payment determination for other impacted ACOs.

[1] Korvink, Michael et al, "A Novel Approach to Developing Disease and Outcome-Specific Social Risk Indices," *American Journal of Preventive Medicine,* May 3, 2023, https://www.ajpmonline.org/article/S0749-3797(23)00203-9/fulltext

Premier's Recommendation

Premier supports CMS' proposal to codify a process for reopening payment determinations in instances where improper payments have been identified, including an option by which ACOs can request a reopening. This proposal is responsive to ongoing concerns from ACOs around the negative impact of bad actors on both the Medicare trust funds as well as ACOs ability to succeed in the MSSP. Premier urges CMS to provide additional clarity around the types of considerations it would give when determining if an improper payment is of sufficient magnitude to reopen a determination. Premier also urges CMS to consider what information is critical for it to receive from ACOs when an ACO is requesting a reopening and that it develop the least burdensome process possible.

MITIGATING THE IMPACT OF SIGNIFICANT, ANOMALOUS AND HIGHLY SUSPECT BILLING ACTIVITY ON MSSP PROGRAM FINANCIAL CALCULATIONS IN 2024 OR SUBSEQUENT YEARS

Background and Proposal

Over the last several months, many stakeholders, including Premier, have continued to raise concerns around the impact of increased billing for intermittent urinary catheter supplies in 2023 on MSSP program expenditures. As Premier and other stakeholders highlighted in a recent letter to CMS, Medicare spending on the two catheter codes saw a nearly 20-fold increase between 2021 to 2023 – with spending increasing from $153 million to $3.1 billion. Nearly all of this increase was attributed to only ten suppliers.

In June, CMS released a standalone regulation to address the impact of this significant, anomalous and highly suspect (SAHS) billing on MSSP expenditures in 2023. In its comments, Premier applauded CMS for taking swift action to address these concerns to ensure that MSSP ACOs are held harmless from this SAHS activity that is outside the control of the ACOs.

As part of CY 2025 PFS rule, CMS proposes to establish a process that would allow it to proactively make similar adjustments to MSSP expenditures should new SAHS billing activity be identified for PY 2024 or subsequent years. Under this proposal, CMS would notify ACOs at the start of a calendar year of its determinations as to which codes, if any, warrant adjustments for the prior performance year. The adjustments would be made to the MSSP program calculations as part of the annual financial reconciliation process.

In the proposed rule, CMS identifies several criteria that it would consider in determining whether SAHS billing activity warrants removal from MSSP financial calculations, such as:

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

In the event that CMS identifies one or more HCPCS or CPT codes with SAHS billing activity, it would remove all Medicare Parts A and B payment amounts associated with the codes from expenditure and revenue calculations for the relevant calendar year. CMS would also adjust the three most recent years prior to the start for the ACO's agreement period for purposes of establishing historical benchmarks used in PY reconciliation.

Premier's Recommendations

Premier applauds CMS for continuing to be responsive to the concerns we have raised around the negative impact anomalous billing has had on MSSP ACO financial performance. Premier appreciates CMS taking a comprehensive approach to excluding all claims for these services from both performance year and benchmark expenditures. This methodology is the most straightforward and will help to minimize complications in the recalculation of expenditures for these years.

CMS proposes to notify ACOs on annual basis after the conclusion of the performance year if it determines there has been SAHS activity that warrants removal of claims from MSSP expenditures. ***Premier urges CMS to maintain flexibility to notify ACOs sooner, such as on a quarterly basis, if it determines SAHS billing activity occurred earlier in the year***. For example, while CMS addressed the catheter billing issue for PY 2023 in a standalone rule, the issue persisted into the first quarter of PY 2024. Under this scenario, it would be reasonable for CMS to notify ACOs sooner than early 2025 that they plan to take action to address this SAHS activity.

Furthermore, Premier encourages CMS to maintain consistency between benchmark years and performance years when removing SAHS activity. For example, if expenditures for an entire code are removed from an ACO's benchmark, it would be appropriate for CMS to notify the ACO that expenditures for that code will be removed for all remaining performance years in the current agreement.

As noted in our prior letter, ***Premier believes that ACOs are well positioned to detect anomalous billing given their ongoing and in-depth analysis of claims and utilization data***. The HHS Office of Inspector General has previously highlighted the value that ACOs can bring in uncovering potential fraud, waste and abuse, recommending that CMS prioritize referrals from ACOs. To that end, ***Premier continues to urge CMS to work with ACOs to improve the process for reporting suspected fraud, waste and abuse and to explore new opportunities to deepen its partnership in promoting high-quality and efficient patient care.***

ESTABLISHING HIGHER RISK AND POTENTIAL REWARD UNDER THE ENHANCED TRACK

Background

For the last couple of years, CMS has sought stakeholder input on the development of a higher risk MSSP option under which the shared savings/loss rate would be somewhere between 80 to 100 percent, building on the experience of the Next Generation ACO (NGACO) and ACO REACH Models. As part of this year's rulemaking cycle, CMS seeks input on a participation option that would allow for higher risk and reward that would replace the current ENHANCED track. CMS is concerned that if both an ENHANCED and a higher track were available, the highest-performing ACOs would self-select into the higher of the two risk tracks, which would reduce savings to the Medicare program.

Premier's Recommendations

Premier strongly supports adoption of a higher risk track option within MSSP, which is an opportunity to build on the lessons learned from the NGACO and ACO REACH models. The NGACO Model, in particular, had offered participants the opportunity to elect for full financial risk in exchange for additional flexibilities and incentives that are not available in MSSP. As we had noted previously, Premier was disappointed that the Administration did not extend this model following its conclusion in 2021. At that time, Premier had strongly urged CMS to re-evaluate the model for expansion and consider other options for model permanence, such as a higher risk track in MSSP. With its conclusion, participants were faced with the choice of moving into MSSP (and taking on lower financial risk) or moving to the Direct Contracting model, where they would be required to take on capitation, a function that many ACOs have not taken on previously and did not have the resources to deploy. Premier encourages CMS to look to the design of the NGACO model when adopting a higher risk track within MSSP.

While we are supportive of a higher risk option in MSSP, Premier strongly opposes replacing the existing ENHANCED Track with the higher risk track. Not all ACOs will be in a position to take on increased risk. By removing the ENHANCED track as an option, CMS may inadvertently push some ACOs out of MSSP that may be unable to take full (or close to) full risk under the new higher risk track.

As CMS considers the design of a higher risk track, Premier encourages CMS to consider the following:

- ***Align policies under the higher risk track with existing MSSP policies and methodologies, while including options for enhancements to those taking on higher risk.*** Instead of developing completely new methodologies, Premier encourages CMS to model the higher risk track off of existing policies in the lower risk tracks, with additional options for the ACOs. For example, CMS should allow ACOs to select between the existing symmetric MSR/MLR selection options available for ACOs under two-sided risk, while allowing ACOs the option to take on even more exposure to both positive savings and negative risk with a symmetric MSR/MLR of 0 percent. Additionally, CMS should give ACOs the option of varying truncation levels in exchange for higher potential of shared savings. Under the existing framework, ACOs may have limited incentive to work with the highest risk or sickest patients once they pass a certain spending limit, which ultimately results in CMS absorbing the costs of unmanaged care for this population. CMS should give experienced ACOs the opportunity to modify the methodology to encourage them to work with the highest cost beneficiaries, increasing both the potential for shared savings to the ACO, as well as savings to CMS.
- ***Apply a discount only if an ACO takes on full risk and is therefore eligible for 100 percent shared savings.***
- ***Work with stakeholders to identify best practices from the ACO REACH model that should be carried forward to MSSP.***

Finally, Premier continues to urge CMS to utilize MSSP as an innovation platform and to harmonize policies across initiatives and scale best practices. ACOs participating in MSSP should not have to leave this permanent program to take on more advanced risk or to utilize new flexibilities or enhancements being tested under other models. To that end, Premier recommends that CMS adopt the following policies:

- ***Providing a glide path to capitation.*** Premier has long advocated for a model which allows an ACO to establish primary care capitation and bundled payments within the ACO. CMS should provide MSSP participants a similar option which would allow them to reduce a certain percentage of fee-for-service payments in exchange for receiving a prospective population-based payment.

CMS has employed similar methodologies in Direct Contracting/ACO REACH and NGACO, such as through the All-Inclusive Population-Based Payment (AIPBP). This option should be available to all ACOs under two-sided risk regardless of their MSSP track.

- ***Testing new options for alignment.*** To achieve CMS' goal of getting all Medicare beneficiaries into a care relationship accountable for quality and total cost of care by 2030, we must think beyond primary care attribution approaches. CMS should consider testing new approaches for aligning beneficiaries, such as through other types of non-primary care providers (e.g., specialists) or based on the ACO's affiliation with Medicaid Managed Care Organizations (MCOs). Additionally, MSSP ACOs currently can only voluntarily align beneficiaries through Medicare.gov. CMS should provide ACOs with additional options to voluntarily align beneficiaries, such as through paper-based forms or their own websites, which has the potential to increase beneficiaries' engagement in MSSP and help improve policy alignment across total cost of care initiatives.

- ***Establishing additional benchmark options based on patient population and clinical need*****,** especially for complex patient populations. To drive innovation in care, providers need adequate budgets to meet the care needs of various populations. CMS has recognized the need to modify benchmarking approaches to meet the needs of certain populations through other models, such as the High Needs Population track under ACO REACH. Premier urges CMS to consider additional benchmarking approaches for certain high-needs or high-cost Medicare populations. This approach will be critical as CMS seeks to align additional beneficiaries with APMs. Unassignable beneficiaries typically have not received primary care services and are frequent emergency department users. As a result, current benchmarking and risk adjustment approaches, which are based on historical claims, are unlikely to capture the costs of these patients.

- ***Offering enhanced waivers or benefits.*** CMS should expand the types of waivers and enhancements available under MSSP to match those that are offered under the NGACO and ACO REACH. For example, CMS should improve the MSSP Beneficiary Incentive Program to match flexibilities granted under the NGACO model. CMS should also look to adopt flexibilities granted under the COVID-19 PHE, such as hospital at home model and additional telehealth flexibilities.

BENEFICIARY NOTIFICATION REQUIREMENTS

Background and Proposals

As part of CY 2023 rulemaking, CMS modified the frequency of required beneficiary notifications from a minimum of once per performance year to once per agreement period. As part of this, CMS finalized a new requirement that ACOs provide an additional follow-up notification with beneficiaries at either the beneficiary's next primary care service visit with an ACO professional or no later than 180 days after the initial beneficiary notice was provided. The follow-up communication, which can be delivered verbally or in writing, is intended to provide the beneficiary a meaningful opportunity to engage with an ACO representative and to ask questions. ACOs are required to track and document the follow-up engagement and make documentation available to CMS upon request.

ACOs that select preliminary prospective assignment with retrospective reconciliation ("retrospective ACOs") are currently required to provide the standardized written beneficiary notice to all fee-for-service beneficiaries before or at the first primary care service visit during the first performance year in which the beneficiary receives a primary care service from an ACO participant.

Based on feedback from stakeholders like Premier, CMS proposes modifications to its beneficiary notification policy to require ACOs to provide the follow-up communication within 180 days of the initial written notification – removing the requirement that it be the earlier of the next primary care visit or 180 days from initial notification. Additionally, CMS proposes changes to notification requirements for retrospective ACOs to require the written notification to only a subset of the Medicare fee-for-service beneficiary population that is more likely to be assigned to the ACO (i.e., beneficiaries who received at least one primary care service from an ACO provider during the assignment window).

Premier's Recommendations

Premier strongly supports the proposed changes to beneficiary notification requirements, which will reduce administrative burden and make notification processes less confusing and onerous for ACOs and beneficiaries alike. As we have highlighted previously, it has been challenging for ACOs to design processes to ensure compliance with the timing of the notification, which requires the follow-up communication to occur at the earlier of the beneficiary's next primary care visit or 180 days after the initial communication. Since ACOs often do not have real-time insight into when a primary care visit occurs, some ACOs are considering sending the follow up notification soon after the initial notification or requiring the follow-up communication to occur at every primary care visit to ensure compliance with the requirement. This introduces additional burden on ACO professionals, as well as increases potential confusion for beneficiaries. Modifying the policy to within 180 days of the initial notification, will ensure ACOs have the flexibility to conduct the follow-up in a way that is most meaningful for their patients and to allow them to establish straightforward protocols to comply with the requirements.

Premier is concerned that efforts to modify notification requirements for retrospective ACOs fall short of what is needed to see operationalized change. So long as the timeframe requirements for notification remain (prior to or during first primary care service of the year), a majority of retrospective ACOs will likely need to continue to notify all fee-for-service beneficiaries to ensure compliance because in-person notification is the most efficient and effective approach. Based on our work with multiple retrospective ACOs, it is not reasonable to ask practice staff to differentiate at the point of service between all fee-for-service beneficiaries and MSSP attribution eligible beneficiaries.

Premier recommends eliminating or modifying the "prior to or during first primary care service of the year" requirement to allow ACOs to own the process while also reducing over notification of beneficiaries that is necessary to ensure compliance with the current and proposed requirements. Specifically, allowing retrospective ACOs to utilize the quarterly preliminary prospective attribution list as the notification list would accomplish this. It could also be appropriate to place a 90-day notification deadline after the release of each list to bring the notification as close as possible to the actual utilization of primary care services.

Notification is only one of many ways to improve beneficiary's understanding of ACOs and value-based care. ***Premier continues to encourage CMS to work with stakeholders, including beneficiary advocates and caregivers, to develop new policies and flexibilities that allow ACOs to better engage with beneficiaries in meaningful ways.*** For example, Premier encourages CMS to consider adopting the following policies:

- CMS should modify the definition of "marketing materials and activities" in MSSP to distinguish between education/communication and marketing and facilitate more ACO-developed education

for beneficiaries. Medicare Advantage (MA) plans, for example, define marketing materials as a subset of communications, which allows MA plans to communicate more freely with beneficiaries.
- CMS should expand and prioritize information on ACOs in the Medicare and You handbook so that beneficiaries interested in learning more have an accessible and widespread resource to refer back to. Currently, there are only two paragraphs towards the end of the handbook dedicated to ACOs and Premier sees an opportunity to expand upon what ACOs provide to beneficiaries and reduce confusion.
- CMS should allow ACOs to edit beneficiary notification templates to include more ACO-specific information, provided all required core elements are included, and to translate notifications into languages that best serve their targeted population. For example, ACOs should be allowed to include the clinician's name or name of practice, which is more recognizable to patients than the ACO name.
- To ensure beneficiary representatives accurately reflect ACO-aligned beneficiaries, Premier encourages CMS to develop guidance or requirements for beneficiary incentive payments to those who are beneficiary representatives to support low-income beneficiaries taking an active role in their ACO.

These recommendations will support active beneficiary engagement beyond a required notification.

ALIGN CEHRT REQUIREMENTS FOR MSSP ACOS WITH MIPS

Background and Proposals

MSSP ACOs are currently required to certify at the end of each performance year use of certified EHR technology (CEHRT) by their participating clinicians. These requirements differ depending on if an ACO is in a track of MSSP that meets the financial risk standards to be considered an Advanced APM. For ACOs that are in a track that does not meet the financial risk standard, the ACO must certify that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT. For ACOs that are in a track that does meet the financial risk standards to be an Advanced APM, the ACO must certify that at least 75 percent of eligible clinicians participating in the ACO use CEHRT, which is the threshold established under the Quality Payment Program (QPP).

As part of CY 2024 rulemaking, CMS modified this policy to align the MSSP requirement with MIPS. Under the policy, CMS plans to sunset the current MSSP requirements at the end of PY 2024 and instead require reporting of the MIPS Promoting Interoperability (PI) performance category measures (and scoring) either at the individual, group or virtual group level or by the ACO as an APM entity, beginning with PY 2025.

Premier's Recommendations

Premier continues to strongly oppose this policy for multiple reasons, including the excess burden it places on ACOs and clinicians, the policy's contradiction to the statutory exemption from MIPS as a key incentive for clinicians to participate in Advanced APMs and the failure of the policy to recognize the key distinctions between ACOs and individual clinicians or groups*.*

This policy introduces additional burden to ACOs (or individual clinicians), which are already overburdened and facing upcoming changes which will impact their stability, including the expiration of Advanced APM Incentive Payments at the end of CY 2024. In addition, according to statute, QPs in an Advanced APM are exempt from MIPS, which is a valuable incentive for clinicians to join an Advanced APM. Removing this

incentive and requiring these clinicians to meet MIPS PI requirements would be counter to CMS' overall stated goal for all Medicare fee-for-service beneficiaries to be part of care relationships with accountability for quality and total costs by 2030. Encouraging participation in the MSSP and in Advanced APMs is central to achieving that goal.

While Premier appreciates the goal of ensuring compliance with CEHRT criteria, Premier strongly believes that the underlying premise of aligning MSSP with MIPS is fundamentally flawed. As we note above, it fails to recognize the unique role of ACOs as compared to clinicians. Most notably, ACOs are a network of aligned providers that furnish coordinated care across the care continuum. MIPS measures quality on the basis of point-in-time encounters by individual clinicians and groups. Aligning the MSSP with MIPS for the sake of alignment is superfluous to the ultimate goal of moving from volume to value. If the ultimate goal is to incentivize care relationships with accountability for quality and costs, CMS should prioritize establishing policies designed for ACOs and the MSSP specifically, instead of forcing ACOs to align with requirements that are not structured around their unique composition and frameworks. These policies should be focused on their characteristics and challenges to minimize burden so that clinicians are incentivized to move to APMs, as well as continue their participation in APMs.

Premier strongly urges CMS to repeal the new CEHRT requirements. At a minimum CMS should delay these policies until at least the 2027 performance year and establish additional flexibilities, such as exceptions for new APM entities and practices, and applying the existing small practice exemption to practices in ACOs.

REVISIONS TO THE DEFINITION OF PRIMARY CARE SERVICES USED IN MSSP BENEFICIARY ASSIGNMENT

Background and Proposals

CMS maintains a list of HCPCS/CPT codes that are used to identify primary care services for purposes of assigning beneficiaries to ACOs.

CMS proposes to amend the definition of primary care services used in the assignment methodology to include several additional codes that are either being adopted as new codes under the PFS or that CMS now recognizes as preventive services and should be included in the primary care definition.

Premier's Recommendations

Premier is generally supportive of continuing to align the primary care service definition used in the MSSP with updates to codes under the PFS. Premier also recognizes that expanding the primary care service definition used in the assignment methodology will correspondingly have the potential for expanding the scope of beneficiaries who are assignable to an ACO. ***Premier urges CMS to continue to monitor the impact of expanding the definition of primary care services to include the additional PFS codes on beneficiary assignment***. This includes identifying any patterns in population types and characteristics that may be captured by the additional codes and determining the effect that the additions to the definition may have ACO assignment. Premier also encourages CMS to respond to any identified unintended consequences and consider changes to mitigate any such unintended consequences in a timely manner.

ELIMINATE HIGH-LOW REVENUE DISTINCTION

Background

Under *Pathways to Success*, CMS began distinguishing between high- and low-revenue ACOs as a means of differentiating ACOs by type of provider (e.g., hospital-led vs. physician-led ACOs). This policy is built on the dual-premise that: 1) physician-owned ACOs (low-revenue) perform better than hospital-led (high-revenue) ones; and 2) that low-revenue ACOs have less ability to control expenditures for beneficiaries.

Premier's Recommendations

Premier continues to strongly urge CMS to eliminate the high-low revenue distinction in MSSP, which is flawed and creates market distortions by advantaging one provider type over another.

CMS has continued to state its belief that low-revenue ACOs outperform high-revenue ACOs, highlighting that low-revenue ACOs have historically had better financial performance than high-revenue ACOs. However, a Premier analysis found that differences between high-revenue and low-revenue ACOs may be driven by other factors beyond ACO composition. Findings include:

- ***Low-revenue ACOs have more flexibility in selecting providers in certain locations, meaning they may be better able to reduce spending and achieve savings targets.*** Premier's analysis found that high- and low-revenue ACOs operate in distinctly different geographies, with high-revenue ACOs providing care to more beneficiaries and operating in more diverse areas. This suggests that high-revenue ACOs (i.e., hospital-led) may have less flexibility to select providers who are operating in more favorable areas.

- ***High-revenue ACOs serve higher cost beneficiaries attributed through specialists.*** Premier's analysis found that high-revenue ACOs receive a significantly higher proportion of attributed lives through specialist attribution. Even after accounting for risk, beneficiaries that are attributed through specialists appear to have higher costs than others in a given region when compared to beneficiaries that are attributed through primary care providers.

- ***No significant differences in performance could be found once adjustments accounted for differences in attribution and geography.*** Prior to accounting for risk and geographic normalization, Premier's analysis found that low-revenue ACOs appear to outperform high-revenue ACOs by 3-4 percent, similar to CMS' findings. However, once applying a more refined comparison of the regional efficiency of high- and low-revenue ACOs, Premier found that difference in performance shrinks to 1-2 percent. Furthermore, after controlling for ACO churn by including only ACOs that have participated for three or more years, Premier found there is no significant difference between high-revenue versus low-revenue ACO performance.

These findings demonstrate that other factors outside an ACO's control, such as geographic location or attribution, are more significant factors that explain differences in ACO financial performance. Continuing to distinguish ACO participants as high-revenue versus low-revenue creates an unlevel playing field that disadvantages hospital-led ACOs relative to their physician-led counterparts.

To achieve its goal of getting all beneficiaries into an accountable care relationship by 2030, CMS will need to craft ACO policies that do not limit provider participation and encourage ACOs to enter into less attractive markets. The best way to drive high-quality care for patients is to create incentives that drive all providers

to collaborate and innovate to deliver high-quality, cost-effective healthcare. Unfortunately, the high-low revenue distinction has discouraged partnership with certain types of providers, such as hospitals and specialists. Eliminating the high-low revenue distinction will ensure that high performers are encouraged to participate in models regardless of provider type and will allow providers to more effectively collaborate in ways that best meet the needs of their population.

III. PROPOSED NEW MEDICARE BILLING CODES

Background and Proposals

Payment for caregiver training services. As part of CY 2024 rulemaking, CMS finalized a policy to allow payment for behavioral management/modification training for guardians/caregivers of patients with a mental or physical health diagnosis (CPT codes 96202 & 96203) and Caregiver training in strategies and techniques to facilitate the patient's functional performance (CPT codes 97550-97552) based on an established therapy plan.

As part of the CY 2025 PFS rule, CMS proposes to establish new HCPCS coding (GCTD1-3) and payment for caregiver training for direct care services and supports. Unlike other caregiver training codes that are currently paid under the PFS, the caregiver training codes for direct care services and support focus on specific clinical skills aimed at the caregiver effectuating hands-on treatment, reducing complications, and monitoring the patient.

CMS also proposes to establish new coding (CPT codes GCTB1 & GCTB2) and payment for caregiver behavior management and modification training that could be furnished to the caregiver of an individual patient. (Current CPT coding only allows for caregiver training service to be furnished in a group setting with multiple sets of caregivers of multiple beneficiaries).

Services addressing health-related social needs. As part of CY 2024 rulemaking, CMS created new provider billing mechanisms for three types of social need-related services: Community Health Integration (CHI), Principal Illness Navigation (PIN) and SDOH Risk Assessments. Specifically, CMS finalized:

- *Community Health Integration* (G0019, G0022) describing CHI services performed by certified or trained auxiliary personal, which may include a Community Health Worker, incident to the professional services and under the general supervision of the billing practitioner.
- *Principal Illness Navigation* (G0023, G0024) and *Principal Illness Navigation-Peer Support* (G0140, G0146), which parallel the CHI services, but focused on patients with a serious, high-risk illness who may not have SDOH needs.
- *Social Determinants of Health Risk Assessment* (G0136) for the work involved administering an evidence-based SDOH risk assessment when medically reasonable and necessary in relation to an E/M visit to inform the diagnosis and treatment plan.

As part of CY 2025 rulemaking, CMS is seeking input on potential refinements to these policies.

Premier's Recommendations

Premier applauds CMS' ongoing efforts to further advance health equity through the Medicare program and supports CMS' proposal to further expand on last year's policies to include additional billing codes that compensate providers and caregivers for the work they already do to best serve those with complex medical

needs and SDOH concerns. ***Premier continues to urge CMS to consider ways to better align data collection requirements and reimbursement across Medicare payment systems***. For example, hospital staff may conduct social risk screening during a patient's inpatient stay as part of the Inpatient Quality Reporting program and receive no additional reimbursement to fulfill this requirement. Yet, the same patient may be screened by a provider in an outpatient setting who would be able to bill under the PFS for the new SDOH Risk Assessment code. ***Premier believes it is critical that important social risk factor data is captured as efficiently as possible by the right provider in the right setting***. CMS should consider whether requiring any additional data collection without adequately adjusting reimbursement is equivalent to an unfunded mandate.

Additionally, Premier applauds CMS' ongoing recognition for the need to create incentives to help advance health equity. However, addressing the underlying social and economic inequities as well as systemic barriers and biases that drive disparities in care requires (1) data collection and monitoring of key outcomes and health equity measures; and (2) shifting the payment system to account for a more comprehensive set of services that address disparities.

To further advance efforts to address health equity, ***Premier recommends that CMS focus on improving data collection and standardization, which is vital to providers' success in driving towards health equity as it will foster the development and sharing of best practices within and among clinical settings, health systems and delivery system designs***. The Agency for Healthcare Research and Quality (AHRQ) has found that one of the biggest barriers most health systems face in improving quality and reducing disparities within their own walls is systematically identifying the populations they serve, addressing the needs of these populations and monitoring improvements over time.[2] AHRQ further found that the principal challenges in obtaining race, ethnicity and language data for use in quality improvement assessments include a lack of standardization and understanding of why the data are being collected.

To help foster better data collection and standardization, CMS should adopt incentives, such as quality program bonuses, to help encourage standardized data collection. Additionally, CMS should invest in educating both patients and providers about the importance of collecting SDOH information, the evidence for how it affects care and existing privacy requirements under HIPAA that safeguard information patients share with their providers. Finally, Premier encourages CMS to evaluate the standards that hospitals and other entities already have in place to advance health equity. This creates opportunities for CMS to build on and create synergies where possible on existing efforts as CMS and other federal partners work towards a national standard.

IV. TELEHEALTH AND OTHER SERVICES INVOLVING COMMUNICATION TECHNOLOGIES

Background and Proposals

Telehealth was a critical tool during the COVID-19 PHE, allowing providers to continue to furnish much-needed services to patients from the safety of their homes. One of the flexibilities that CMS granted was to allow for telehealth services to be furnished using audio-only technology.

As part of this year's rulemaking cycle, CMS proposes to revise regulations to state that an interactive telecommunications system may also include two-way, real-time audio-only communication technology for

[2] https://www.ahrq.gov/research/findings/final-reports/iomracereport/index.html

any telehealth service furnished to a beneficiary in their home if the patient is not capable of or does not consent to the use of video technology. Under this policy, the distant site physician or practitioner must be technically capable of using an interactive telecommunications system that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication.

Premier's Recommendation

Premier strongly supports CMS' proposal to allow for beneficiaries to use audio-only technology under certain circumstances. Accessing video technology can be particularly challenging and creates barriers for beneficiaries who are low-income, elderly, disabled or who live in rural areas where the broadband infrastructure cannot support streaming video. The COVID-19 PHE has highlighted that many services can be effectively delivered as audio-only and do not require a video-connection

Premier continues to believe that telehealth services offer the ability to enhance medical management between patients and providers, enable remote monitoring, and greatly improve communication and education between primary and specialty care providers. Ultimately, Premier recognizes that CMS has limited statutory authority to expand telehealth services following conclusion of the current Congressional expansion which is set to expire at the end of CY 2024. Therefore, ***Premier continues to urge CMS to work with Congress to adopt broader telehealth reforms.***

V. REQUIREMENTS FOR ELECTRONIC PRESCRIBING FOR CONTROLLED SUBSTANCES FOR A COVERED PART D DRUG UNDER A PRESCRIPTION DRUG PLAN OR AN MA-PD PLAN

Background and Proposals

Section 2003 of the SUPPORT Act generally mandated that the prescribing of a Schedule II, III, IV or V controlled substance under Medicare Part D be done electronically beginning Jan. 1, 2021. Over the last several years, CMS has finalized various policies to operationalize the Electronic Prescribing for Controlled Substances (EPCS) Program consistent with this statutory requirement. As part of 2022 rulemaking, CMS delayed the date by which it would pursue compliance action against prescribers of Part D controlled substance prescriptions for beneficiaries in long-term care (LTC facilities) to Jan. 1, 2025. This came in recognition of some of the technological barriers that prescribers who work in or provide care to residents in LTC facilities faced.

As part of the Part D and Health IT Standards Final rule released in June 2024, CMS had finalized the requirement that Part D sponsors, prescribers and dispensers, when electronically transmitting prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals comply with the use of NCPDP SCRIPT standards as specified in 45 CFR 170.205(b). Taken in conjunction with the standards and expiration dates adopted by the Office of the National Coordinator for Health Information Technology (ONC), the NCPDP SCRIPT standard version 2023011 will be required for the CMS EPCS Program by Jan. 1, 2028. Until then, entities can use either NCPDP SCRIPT standard version 2017071 or NCPDP SCRIPT standard version 2023011.

In light of the changing standards, CMS proposes to push back the date by which it would determine compliance for prescriptions written for a beneficiary in a LTC facility until Jan. 1, 2028, which would align with the date by which entities must use NCPDP SCRIPT standard version 2023011.

Premier's Recommendations

Premier supports CMS' proposal to align compliance with the EPCS Program for LTC prescribers with the timeline for the NCPDP SCRIPT standard version 2023011, which Premier has previously advocated for. Premier agrees with CMS' assessment that this delay will help minimize burden on pharmacists and pharmacies by ensuring they do not need to adapt to two different standards, especially in light of the need for additional guidance around the updated standard version 2023011. Premier urges CMS to continue to work with the LTC pharmacy community in advance of CY 2028 to evaluate if additional barriers to implementation exist and consider additional delays in enforcing compliance as needed.

Additionally, Premier continues to urge CMS to support wider adoption of interoperable health information technologies across the healthcare spectrum and particularly in LTC and post-acute care (LTPAC) settings of care. Inequitable access to and use of interoperable health IT persists across the LTPAC continuum. As a result, it is more difficult to broaden data exchange between stakeholders, especially during instances of shared care and transitions of care between hospitals and the LTPAC sector. Unfortunately, the rate of adoption and use of interoperable health IT among LTPAC providers lags far behind acute and ambulatory care providers as programs authorized and funded under the Health Information Technology for Economic Clinical Health (HITECH) Act excluded LTPAC providers. The time is ripe to address technology challenges faced by these sectors so that we can move towards comprehensive bidirectional data exchange, improved patient outcomes, streamlined data collection and reporting, and so much more.

VI. BUILDING UPON THE MIPS VALUE PATHWAYS (MVPS) FRAMEWORK TO IMPROVE AMBULATORY SPECIALTY CARE

Background

CMS introduced the MIPS Value Pathway (MVP) concept during the CY 2020 PFS rulemaking cycle and views MVP reporting as the "future state of MIPS" and a bridge for clinicians from traditional fee-for-service care delivery to APM participation. MVPs are intended to provide MIPS eligible clinicians with a cohesive subset of measures and activities on which to report related to a specific specialty or condition.

CMS is considering ways that it may utilize the MVP framework to develop an ambulatory specialty care model. Instead of a MIPS payment adjustment, participants under this model would receive a payment adjustment based on a set of clinically relevant MVP measures that they would be compared against a pool of other model participants (of the same specialty type and clinical profile) required to report on the same MVP measures. CMS seeks comment on various aspects of this potential model, including possible mandatory approaches. CMS notes that any mandatory model would be implemented through future rulemaking and it does not expect a model would be implemented before 2026.

Premier's Recommendations

While Premier views MVP reporting as a potential step towards APM participation for some clinicians, we would caution CMS to work with specialty care groups to design an ambulatory MVP model. The transition to MVPs will be inherently limited by the large numbers of clinicians that are exempt from MIPS reporting and that presumably will also be exempt from mandatory MVP reporting. Further, the optimal relationship between MVPs and APMs remains unclear. Premier continues to urge CMS to design MVPs so that providers are prepared and better incented to adopt APMs. Requiring MVPs to include a population health measure and incorporating health equity measures over time is a step towards

encouraging movement into APMs. However, every aspect of MVPs should be designed to encourage the movement to APMs, including measure scoring and weights, multispecialty group/subgroup reporting composition and reporting exceptions. APM measures should be translated for use in MVPs rather than the converse, and Premier reiterates our previously expressed objection to forcing APM measures into a MIPS format as is being done in the MSSP, which is misaligned and counterproductive to moving from volume-to-value. Alignment will be served by developing MVPs that center on quality improvement, efficient resource use, patient outcomes and technology to improve care for specific patient populations or conditions. To that end, ***Premier strongly urges CMS to work with stakeholders, such as specialty care societies, to co-design an ambulatory specialty care model using the MVP framework.***

Premier also urges CMS to consider other ways to better foster specialist engagement in value-based care, including integration into ACOs. In November 2022, CMS released its Innovation Center strategy for supporting access to high-quality integrated specialty care. At the core of that strategy was an acknowledgement of the need to develop episodic payments in coordination with total cost of care models and to ensure ACOs have the necessary flexibilities and policies in place to support partnership and integration with specialists. There are several ways that CMS can better support integration of specialists into ACOs:

- ***Allow entities to define capitation or bundled payment approaches within a total cost of care arrangement – either through "shadow" bundles established by the ACO or through CMS-established bundled payment programs.*** CMS can support ACOs in developing shadow bundles by providing additional data on specialist performance and by developing best practices or standards for defining episodic care. CMS should also explore developing a capitated payment option for ACOs that wish to engage with specialists on select chronic conditions.

- ***Testing new types of beneficiary attribution.*** Existing ACO attribution methodologies focus on plurality of primary care services, which can result in a low volume of patients being aligned to the ACO through the specialists. As a result, many specialists may not find it worthwhile to engage with the ACO. CMS should test other forms of attribution or alignment, such as voluntary alignment through specialists or other providers.

- ***Modify risk adjustment and benchmarking methodologies to better account for complex and high-needs populations.*** Currently, the financial methodologies under ACOs do not appropriately account for patient clinical risk, especially for complex populations. The current benchmarking and risk adjustment methodologies favor patients who are attributed based on primary care services. As a result, benchmarks are often artificially lower for certain high-cost patient populations, which can disincentivize inclusion of specialists in ACOs. CMS should explore ways to further stratify benchmarking based on patient risk factors. For example, in recent years we have seen a rapid increase in Part B drug costs for oncology patients. These increased costs are not sufficiently accounted for in existing benchmarking or risk adjustment methodologies, resulting in losses for ACOs that may serve a large oncology population. To better account for these high-cost patients, CMS should further stratify its current benchmarking approach to set separate benchmarks for patients with certain high-cost chronic conditions or treatments. Finally, CMS should explore use of the concurrent HCC risk adjustment model under MSSP for high-needs patients or patients with complex medical needs.

- ***Evaluate the impact of policy changes on inclusion of specialists.*** When developing policies, CMS must consider the unintended consequences that may result in ACOs narrowing the network of providers they work with. For example, the high-low revenue distinction in MSSP has

discouraged ACOs from partnering with certain types of providers, such as hospitals or specialists. Additionally, CMS recently finalized significant changes to the MSSP quality reporting requirements and will soon require ACOs to report quality measures from the total population of patients seen by all providers affiliated with the ACO, including specialists. All-payer measurement could significantly impact ACO performance on certain measures where historically certain clinicians (e.g., orthopedist) may have not performed these assessments or measurements (e.g., depression screening) because they are not relevant to or reflective of the clinical care the clinician is furnishing. Given the challenges associated with these new requirements, some ACOs are considering removing specialists from their ACOs.

VII. CONCLUSION

In closing, Premier appreciates the opportunity to submit these comments on the CY 2025 PFS proposed rule. If you have any questions regarding our comments or need more information, please do not hesitate to contact me at 732-266-5472 or soumi_saha@premierinc.com.

Sincerely,

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