The Hospital + Healthsystem Association of Pennsylvania

Leading for Better Health

September 6, 2022

The Honorable Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1770-P
P.O. Box 8016
Baltimore, MD 21244-8016

SUBJECT: CMS-1770-P. Medicare and Medicaid Programs; Calendar Year 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts; Proposed Rule, July 29, 2022

Dear Administrator Brooks-LaSure:

On behalf of The Hospital and Healthsystem Association of Pennsylvania (HAP), which represents approximately 235 member hospitals, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Medicare Physician Fee Schedule proposed rule for calendar year (CY) 2023.

HAP is pleased to see the agency's continued efforts to retain important telehealth flexibilities permitted during the COVID-19 pandemic as well as the delay in implementing the proposal to change how a split visit is defined.

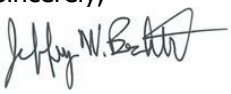
The following comment letter also addresses:

- Reporting requirement for certain single-dose or single-use package drugs
- Opioid use disorder treatment services
- "Incident to" physician services for behavioral health services
- Changes to quality programs

In addition, we incorporate, by reference, all of the comments provided in the American Hospital Association's response to the proposed rule.

Thank you for your consideration of HAP's comments regarding this proposed rule. If you have any questions, contact Kate Slatt, vice president, innovative payment and care delivery, at (717) 561-5317.

Sincerely,



Jeffrey Bechtel
Senior Vice President, Health Economics and Policy

Attachment

HAP
Leading for Better Health

HAP Comments—Physician Fee Schedule
Proposed Rule for Calendar Year 2023

PAYMENT FOR EVALUATION AND MANAGEMENT VISITS

In this rule, CMS proposes delaying the implementation of its policy related to "split" visits for one year, until July 1, 2024.

"Split" Evaluation and Management Visits: Split visits occur when both a physician and a non-physician provider (NPP) provide services during and Evaluation and Management (E/M) visit. Last year, the Centers for Medicare & Medicaid Services' (CMS) proposed to define "substantive portion" as more than half of the total time spent by the physician or the NPP. CMS further proposed that the distinct time of services spent by each physician or NPP furnishing a split visit would be summed to determine total time of the visit. This would establish who provided the substantive portion of the visit and would, therefore, bill for the service.

If a physician performs a substantive portion of the visit, they can bill for the E/M and receive Medicare payment equal to 80 percent of the otherwise applicable payment of the Physician Fee Schedule (PFS), which is the lesser of the actual charge or the fee schedule amount for the service. If the NPP performs a substantive portion of the visit and, therefore, bills for the service, payment is 80 percent of the lesser of the actual charge or 85 percent of the fee schedule rate.

With the proposed delay, the substantive portion would continue to be defined as either one of the three key components of a visit, or more than half the total time through 2023.

While HAP appreciates the proposal to delay this change for one year, CMS' intent to continue to implement this change is troublesome. It does not take into account how clinical workflows are structured. This change also directly contradicts former efforts to reduce administrative burden and will cause significant patient flow inefficiencies at a time when the strain on the health care workforce has never been greater, and the need for patient care has never been more urgent in the wake of COVID-19.

While HAP appreciates the delay in implementing the split visit proposal, HAP strongly urges CMS to resist implementing this proposal in which "substantive portion" is based on time in its entirety. As has been the practice, medical decision-making should determine the appropriate level of E/M visit.

TELEHEALTH

Prior to calendar year (CY) 2021, Medicare had two criteria categories for assessing requests for adding or deleting services from the Medicare telehealth list of services under Section 1834(m) of the Social Security Act:

- Category 1 are services similar to other services already on the Medicare telehealth list
- Category 2 are services that are not similar and, therefore, require additional supporting evidence of clinical benefit

In the CY 2021 final rule, CMS created a new category. Category 3 describes services added during the public health emergency (PHE) for which there is clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence to consider the service as permanent additions under Category 1 or 2 criteria. Category 3 services are to remain on the telehealth list until the end of the PHE.

Undoubtedly, the COVID-19 pandemic has created a world of uncertainty for patients and their health care providers. CMS recognized this uncertainty and the impact the end of the PHE might have on Category 3 services and proposed to retain all Category 3 services until the end of CY 2023 during last year's rulemaking.

In this year's rule, CMS proposes to retain services that are temporarily included on the telehealth list during the PHE but are not on a Category 1, 2, or 3 basis for 151 days following the end of the PHE, as required by the Consolidated Appropriations Act, 2022.

Additionally, CMS proposes adding certain services like psychophysiological therapy and eye exams for established patients to the telehealth list on a Category 3 basis.

Direct Supervision: In the CY 2021 PFS Rule, CMS finalized its proposal to extend the allowance for providers to provide direct supervision via audio/video technology through the end of the calendar year in which the emergency ends or December 31, 2021, whichever is later. CMS is again seeking comment on whether this provision should be made permanent.

While a grim reality, the PHE has been the impetus for advancing access to health care through technology tenfold. Beneficiaries have been able to continue to see their health care provider and do so safely in the comfort of their own home and will continue to demand access to telehealth. The Pennsylvania hospital community is eager to continue working with policymakers at the federal and state level to leverage the experiences of the pandemic and preserve expanded access to care through telehealth, when clinically appropriate.

HAP appreciates the significant actions that CMS is taking in this proposed rule, especially maintaining services that have been temporarily included on the telehealth list during the PHE but are not on a Category 1, 2, or 3 basis for 151 days following the end of the PHE and adding additional services to the telehealth list on a Category 3 basis.

HAP urges CMS to make broad, permanent adoption of any services that were acceptable during the pandemic, given that only services that did not pose significant patient safety concerns were added to the list during this time. As such, we strongly support maintaining Category 3 as a permanent category.

HAP strongly urges CMS to permanently allow direct supervision via audio/video technology.

OPIOID USE DISORDER TREATMENT SERVICES

As a result of the PHE, CMS issued an interim final rule on April 6, 2020, that allowed Opioid Treatment Programs (OTP) to furnish counseling and therapy services using audio-only telephone calls for the duration of the PHE. In this rule, CMS is proposing to allow for continued audio-only telephone services in cases where audio/visual technology is not available to the beneficiary–-defined as circumstances where beneficiaries are not capable or have not consented to the use of devices that permit a two-way, audio/visual interaction permanently.

HAP strongly supports CMS' proposal to permit audio only telephone services permanently as it has become such a critical way to provide access and deliver these important services to beneficiaries.

REQUIRING HOSPITAL OUTPATIENT DEPARTMENTS AND AMBULATORY SURGICAL CENTERS TO REPORT DISCARDED AMOUNTS OF CERTAIN SINGLE-DOSE OR SINGLE-USE PACKAGE DRUGS

Currently, when a provider discards an unused portion of a drug from a single-dose container or single-use package, Medicare pays for the discarded amount as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling. On a Medicare Part B claim, the JW modifier is a Healthcare Common Procedure Coding System (HCPCS) modifier used to report the amount of a drug that is discarded and eligible for payment. Beginning during 2017, in order to more effectively identify and monitor billing and payment for discarded amounts of drugs, CMS began to require the uniform use of this JW modifier for all claims for separately payable drugs with discarded drug amounts from single-use vials or single-use packages payable under Part B. The policy does not apply to drugs that are not separately payable, such as drugs packaged under the outpatient prospective payment system (OPPS) or drugs administered in the Federally Qualified Health Center (FQHC) or Rural Health Clinics (RHC) setting.

The Infrastructure Investment and Jobs Act requires drug manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug beginning January 1, 2023. As such, the CY 2023 PFS proposed rule includes proposals to implement these provisions, including a proposal that hospital outpatient departments (HOPD) and ambulatory surgery centers (ASC) be required to report the JW modifier, or any successor modifier, to identify discarded amounts of refundable single-dose container or single-use package drugs that are separately payable under the OPPS or ASC payment system.

CMS proposes that, for the purpose of calculating the refund amount during a relevant quarter, the JW modifier would be used to determine the total number of billing units of the HCPCS code of a refundable single-dose container or single-use package drug; specifically those with HCPCS codes assigned status indicators "K" or "G" under the OPPS, that were discarded for dates of

service during each quarter. The agency further proposes that the JW modifier would not be required to identify discarded amounts of drugs that are not separately payable, including OPPS drugs with HCPCS codes assigned a status indicator "N" and ASC drugs with HCPCS codes assigned a payment indicator of "N1." Also, CMS proposes to exclude from the refund amount those units of drugs for which payment is packaged into a comprehensive ambulatory payment classification service, i.e. those with an OPPS status indicator of "J1" or "J2." The JW modifier would not apply to drugs administered in the FQHC or RHC setting.

The agency is aware that although use of the JW modifier is currently required, it is often omitted on claims, and it is unclear whether its absence on a claim for a single-dose container drug indicates that there were no discarded amounts or that the modifier was incorrectly omitted from the claim. Therefore, CMS also proposes that HOPDs and ASCs use a separate new modifier, JZ, in cases where no billing units of such drugs were discarded and for which the JW modifier would be required if there were discarded amounts.

CMS also proposes:

- For a drug to meet the definition of "refundable single-dose container or single-use package drug," all national drug codes assigned to the drug's billing and payment code must be single-dose containers or single-use packages, as described in each product's labeling.
- To implement other definitions and exclusions contained in the Infrastructure Investment and Jobs Act, specifically that the term "refundable single-dose container or single-use package drug" excludes drugs that are either radiopharmaceuticals or imaging agents, drugs that require filtration during the drug preparation process, and drugs approved on or after the date of enactment of the Infrastructure Act for which payment under Part B has been made for fewer than 18 months.
- That Medicare review contractors would periodically review Part B medication claims to ensure the JW modifier, JZ modifier and discarded drug amounts are billed appropriately consistent with the agency's normal claims audit policies and protocols.

While HAP certainly understands CMS wanting a way to calculate drug manufacturer quarterly refunds, we have concerns about why this new modifier is even needed, and the administrative burden it creates for hospitals regarding how the agency is proposing to operationalize it.

As described above, since 2017 there has been a process in place requiring the uniform use of the JW modifier for all claims for separately payable drugs with discarded drug amounts from single-use vials or single-use packages payable under Part B. Instead of creating another modifier, which adds complexity to the administrative process and may or may not ultimately be used, to course correct for perceived deficiencies in the use (or non-use) of the JW modifier, additional stakeholder conversation and updated guidance would be preferred, and could ultimately yield more effective outcomes.

Additionally, we would respectfully remind the agency that implementation of a new modifier requires a significant investment of time, staff resources, and funding from hospitals, many of which are still struggling as a result of the COVID-19 pandemic. There is a national workforce crisis and many hospitals are facing bleak financial forecasts, so it seems that the resources required to implement this new and essentially unproven modifier could be much more effectively deployed in other areas.

For these reasons and more, HAP asks that CMS refrain from finalizing these proposals at this time and to continue to analyze if the benefit outweighs the significant burden the proposals would imposed on providers.

"INCIDENT TO" PHYSICIAN SERVICES FOR BEHAVIORAL HEALTH SERVICES

Currently, CMS does not pay separately for professional services of licensed professional counselors (LPC) and licensed marriage and family therapists (LMFT). Payment for these services can only be made under the PFS indirectly when the LPC or LMFT performs services under the direct supervision of the billing physicians or practitioner.

The proposed rule will allow LPCs to provide behavioral health services under general supervision of a physician without the physician being physically present. However, CMS acknowledges that it lacks authority from Congress to add LPCs to Medicare Part B's list of eligible behavioral health providers. Amending the statutory provider list through passage of the bipartisan H.R. 432/S. 828, the Mental Health Access Improvement Act, is necessary to ensure Medicare beneficiaries have access to LPCs and LMFTs.

The proposed change would help with treatment consistency. Numerous times, patients who become eligible for disability or Medicare must transfer to another provider because of the limitations on Medicare eligible providers, which is very unsettling to them.

HAP strongly supports CMS' initiative to amend its current policy and urges Congress to swiftly move H.R. 432/S. 828 through the legislative process to ensure the viability of this proposal. These combined changes would give Medicare clients more options when seeking mental health services and would increase access by freeing up other providers to see an expanded range of patients.

CHANGES TO QUALITY PROGRAMS

Merit-Based Incentive Payment System

CMS is continuing its efforts to refine the Merit-Based Incentive Payment System (MIPS), an incentive program for eligible clinicians that results in positive or negative payment adjustments of up to 9 percent in CY 2023 based on CY 2021 performance.

Specifically, CMS proposes the following:

Quality Category:

- Expanding its definition of high-priority measures to include health equity-related measures and adding a new health equity-related social needs screening measure that would be available beginning with CY 2023 reporting period.
- Changing the timeframe on which performance period benchmarks for administrative claims-based measures are based to data from the performance period itself.
- Increasing the data completeness policy from at least 70 percent of denominator-eligible encounters for each quality measure to 75 percent for CY 2024 and CY 2025.
- Broadening the language adjustor in the case mix adjustment for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) to include any language other than English spoken at home.

Cost Category:

- Retroactively establishing a cost improvement score of up to 1 percentage point starting with the CY 2022 performance period.

Improvement Activity Category:

- Adding four new improvement activities, modifying five existing improvement activities, and removing six existing improvement activities.

Promoting Interoperability Category:

- Making the Query of Prescription Drug Monitoring Program (PDMP) measure a required measure beginning with the 2023 performance period.
- Allowing Advanced Alternative Payment Model (APM) Entities to report Promoting Interoperability at the APM Entity level.

Finally, the rule proposes continuing to use the mean final score from the 2017 performance year/2019 payment year to establish the performance threshold for the 2023 performance year/2025 payment year (the performance threshold would be 75 points).

HAP continues to urge CMS to produce detailed feedback containing actionable data related to the measures included in the cost category. HAP also urges CMS to continue to assess the impact of the PHE on this measure.

HAP strongly supports CMS' efforts to include activities promoting health equity and anti-racism in the MIPS program. Pennsylvania hospitals are committed and engaged in efforts to close health equity gaps. Including this in the quality program allows for further focus and engagement in these critical activities.

MIPS Value Pathways

The CY 2020 rule introduced the general framework for future MIPS Value Pathways (MVP) that CMS believes would align and reduce reporting requirements across the four MIPS performance categories and intended to include specific MVPs in the CY 2021 rule. Due to the PHE, CMS delayed the introduction of MVPs until at least CY 2023 but emphasized its commitment to the intended phase in of MVPs over time.

In this rule, CMS proposes five additional MVPs beginning with the CY 2023 performance period.

Specifically, the MVPs include:

- Cancer care
- Kidney health
- Episodic neurological conditions
- Neurodegenerative conditions
- Promoting wellness

The rule also proposes updates to the seven MVPs finalized in last year's PFS rule and modifications to its processes for establishing and scoring MVP "subgroups" within larger physician practices.

HAP urges CMS to ensure participation in the MVPs remains voluntary until several outstanding issues are addressed including ensuring:

- There are enough measures available to create MVPs applicable to the more than 1 million eligible clinicians that currently participate in the MIPS program
- That using an MVP approach would provide a fair, equitable comparison of performance across clinician and group types and specialties
- That the MVP approach is feasible and not administratively burdensome for multi-specialty group practices

Advanced Alternative Payment Models

CMS also is proposing a key update to its APMs. The rule proposes making permanent its 8 percent generally applicable nominal financial risk standard for Advanced APMs.

HAP supports the proposal to adopt an 8 percent generally applicable nominal risk standard permanently.

Medicare Shared Savings Program

The rule proposes several changes to the Medicare Shared Savings Program (MSSP), many of which are expected to advance equity within the program. CMS proposes making advance

shared savings payments (referred to as advance investment payments [AIP]) to low revenue Accountable Care Organizations (ACO) inexperienced with performance-based risk Medicare ACO initiatives, that are new to the Shared Savings Program, that serve underserved populations. Qualifying ACOs may receive a one-time fixed payment of $250,000, as well as quarterly payments for the first two years of the five-year agreement period.
AIPs would be recouped once the ACO begins to achieve shared savings, under the following terms:

- AIPs would be recouped from any shared savings earned by the ACO in any performance year (PY) until CMS has recouped all AIPs
- If there are insufficient shared savings to recoup the AIPs in a PY, that remaining balance would be carried over to subsequent PYs
- CMS would not recover an amount of AIPs greater than the shared savings earned by an ACO during that PY
- If an ACO terminates its participation agreement during the agreement period in which it received an AIP, the ACO must repay all AIPs it received

ACOs must use these payments to improve health care provider infrastructure, increase staffing, or provide accountable care for underserved beneficiaries, which may include addressing social needs. CMS proposes that the initial application cycle to apply for advance investment payments would occur during CY 2023 for a January 1, 2024, start date.

CMS also is proposing a more gradual transition to performance-based risk. ACOs currently in the BASIC Track Level A or B, and those that begin a Track A or B agreement period on January 1, 2023, would be able to elect to remain there for the remainder of their agreement period. ACOs beginning agreement periods on January 1, 2024, would be able to participate in Level A, for all five years of the agreement period if the following requirements are met:

- The ACO is participating in its first agreement period under the BASIC track
- The ACO is not participating in an agreement period under the BASIC track as a renewing ACO or a re-entering ACO that previously participated in the BASIC track's glide path
- The ACO is inexperienced with performance-based risk Medicare ACO initiatives

These ACOs would generally be eligible for a second agreement period within the BASIC track's glide path, giving two additional years under one-sided models (Levels A and B), for a total of seven years before transitioning on to two-sided risk (Levels C, D and E).

CMS proposes that an ACO determined to be inexperienced with performance-based risk Medicare ACO initiatives, but not otherwise eligible to enter the BASIC track's glide path may enter either the BASIC track Level E for all PYs of the agreement period, or the ENHANCED track. An ACO determined to be experienced with performance-based risk Medicare ACO initiatives would be permitted to complete the remainder of its current PY in a one-sided model of the BASIC track, but would be ineligible to continue participation in the one-sided model after

the end of that PY. Instead, it would be automatically advanced to Level E of the BASIC track at the start of the next PY.
Finally, for agreement periods beginning on January 1, 2024, and after, CMS proposes to allow an ACO to remain in Level E of the BASIC track indefinitely; participation in the ENHANCED track would be optional for all ACOs.
CMS also is proposing modifications to improve the calculation of ACO benchmarks including:

- Incorporating a prospective, external trend factor in growth rates used to update the historical benchmark
- Adjusting ACO benchmarks to account for prior savings
- Reducing the impact of the negative regional adjustment
- Calculating county fee-for-service expenditures to reflect differences in prospective assignment and preliminary prospective assignment with retrospective reconciliation
- Improving the risk adjustment methodology to better account for medically complex, high-cost beneficiaries and guard against coding initiatives
- Increasing opportunities for low-revenue ACOs to share in savings

The rule has several other proposals related to the MSSP including:

- Changes to the trend factor and adjustments used in establishing an ACO's historical benchmark
- Modifying the minimum quality performance standard to allow ACOs that do not meet it to still be eligible for shared savings at a lower rate if they score at the tenth percentile or above on at least one of the four APM Performance Pathway (APP) outcome measures
- Extending the incentive to report the APP measure set through the CY 2024 performance period
- Adopting a "health equity adjustment" beginning with the CY 2023 performance period—CMS proposes to add up to 10 bonus points to the quality performance score of each ACO based on a combination of its performance on each MSSP quality measure and the proportion of its underserved beneficiaries
- Several administrative changes related to ACO marketing, beneficiary notification requirements, and refinements to the skilled nursing facility three-day rule waiver process

HAP appreciates CMS' acknowledgement that all hospitals are not at the same level of readiness to assume risk and its proposal to create pathways that continue to allow inexperienced hospitals to participate in the MSSP. HAP also appreciates the creation of the AIP program and encourages CMS to consider expanding the eligibility criteria to include all ACOs working to combat health inequities.