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Policy Update

CMS Releases CY 2023 Physician Fee Schedule Proposed Rule

On July 7, 2022, the Centers for Medicare & Medicaid Services (CMS) released the CY 2023 Revisions to Payment Policies Under the Physician Fee Schedule (PFS) and Other Revisions to Medicare Part B [CMS-1770-P] Proposed Rule, which includes proposals related to Medicare physician payment and the Quality Payment Program (QPP). Physicians face large, proposed cuts of more than 4% under this year's fee schedule, along with significant proposed changes to Accountable Care Organizations (ACOs), the launch of the Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs), updates to telehealth services, initiatives promoting health equity and other changes to further develop physician quality initiatives.

Key takeaways from the CY 2023 PFS Proposed Rule:

- Proposes a 2023 physician conversion factor (CF) of \$33.0775, representing a 4.4% reduction from the 2022 CF of \$34.6062
- Would implement the statutory extension of coverage for certain telehealth services to 151 days after the end of the public health emergency (PHE)
- Would begin the new MVPs track as a voluntary option to the MIPS in 2023 with 12 different pathways
- Proposes changes to the Medicare Shared Savings Program (MSSP) and introduces new advance investment payments intended to achieve the Administration's goal of 100% participation in accountable care relationships by 2030
- Outlines policies to make behavioral health care easier to access, including addressing the shortage of behavioral health practitioners
- Continues the emphasis on health equity, including how to weave equity into CMS quality reporting programs.

Comments on the proposed rule are due by September 6, 2022.

Read on for a topline summary of the major provisions in the proposed rule.

- The proposed regulation is available <u>here</u>.
- The press release is available <u>here</u>.
- The fact sheet on payment <u>policies</u> is available <u>here</u>.
- The QPP factsheet is available here.
- The MSSP factsheet is available here.
- CMS also issued a <u>blog post</u> on the proposed behavioral health changes.



Major PFS Payment Proposals

Conversion Factor

Medicare physician payment is based on the application of a dollar-based CF to work, practice expense (PE) and malpractice relative value units (RVUs), which are then geographically adjusted. Work RVUs capture the time, intensity and risk of the provider. PE RVUs capture the cost of supplies, equipment and clinical personnel wages used to furnish a specific service. Malpractice RVUs capture the cost of malpractice insurance.

Key Takeaway: The CY 2023 CF would decrease to \$33.0775, a reduction of 4.4%.

Medicare Physician Conversion Factor (2017–2023)		
Year	CF	Actual Update (%)
Jan 1, 2017	35.8887	0.24
Jan 1, 2018	35.9996	0.31
Jan 1, 2019	36.0391	0.11
Jan 1, 2020	36.0896	0.14
Jan 1, 2021	34.8931	-3.32
Jan 1, 2022	34.6062	-0.82
Jan 1, 2023	33.0775	-4.42

The 2023 proposed physician CF is **\$33.0775**. This represents a decrease of **4.42%** from the 2022 CF of \$34.6062. The proposed 2023 anesthesia CF is **\$20.7191**, which represents an approximately **3.91% reduction** from the CY 2022 anesthesia CF of \$21.5623.

The proposed update is based on two factors: a statutory 0% update scheduled for the PFS in CY 2023¹, and a funding patch passed by Congress at the end of CY 2021 through the Protecting Medicare and American Farmers from Sequester Cuts Act signed into law on December 2021. This bipartisan legislation partially mitigated a 3.75% cut to the CY 2022 CF and staved off other Medicare cuts, including a phased-in delay of the Medicare and pay-as-you-go sequestration cuts,

which were triggered by the significant additional spending in the American Rescue Plan enacted in March 2021. The 3% payment patch was only in effect for 2022 and, in the case of Medicare sequestration, was phased out starting April 1, 2022. The overall negative proposed adjustment to the CF is driven by the expiration of the 3% payment patch and a statutorily required budget neutrality adjustment due to other spending increases.

These proposed payment reductions come at a time when physician practices, hospitals that employ physicians and other stakeholders are facing uncertainty about the future of their pandemic recovery, including the duration of the PHE, rising costs due to inflation, staffing shortages and significant challenges from other regulatory burdens (*e.g.*, prior authorization, interoperability requirements and participation in Medicare quality programs such as MIPS). In light of these burdens, the provider community likely will continue to press Congress for relief, although it is unclear whether lawmakers will be able to fully offset the proposed payment reductions. Further congressional action for 2022 is possible, setting up a potential end-of-year Medicare bill that might address 2023 cuts.

¹ The <u>Medicare Access and CHIP Reauthorization Act of 2015</u> established a 0% update for PFS services through 2025. Beginning in 2026, clinicians identified as qualified participants in an Advanced Alternative Payment Model will receive an annual 0.75% update, and all other clinicians will receive a 0.25% annual update.



Specialty Impact

Key Takeaway: The impact by specialty would range from -4% to +5%.

Actual payment rates would be affected by a range of proposed policy changes related to physician work, PE and malpractice RVUs. CMS summarizes the aggregate impact of these changes in Table 138 in the proposed rule. While impact on individual practices would vary based on service mix, the table provides insight into the overall impact of the rule's policies for a specific specialty. Specialty impacts range from - 4% for interventional radiology to +5% for infectious disease. Changes to the CF are not reflected in the impact table.

While some of the differences in specialty impact result from proposed changes to individual procedures, continued clinical labor pricing transition is anticipated to lead to significant decreases in payments for specialties with lower average shares of direct costs attributable to labor. The second-year transition to updated clinical labor pricing, which impacts PE RVUs, in combination with the continued phase-in of previously finalized updates to supply and equipment pricing, likely drive the negative impact for clinical social workers, clinical psychologists, radiology and interventional radiology, vascular surgery and nuclear medicine, summarized in the table below. Specialties with substantially higher average shares of direct costs attributable to labor are anticipated to see significant increases in payment from the second-year transition. Specialties anticipated to benefit from the proposal include infectious disease, geriatrics and internal medicine.

Specialty	Allowed Charges (mil)	Impact of Work RVU Changes	Impact of PE RVU Changes	Impact of Malpractice RVU Changes	Combined Impact
Infectious Disease	\$586	4%	0%	1%	5%
Geriatrics	\$175	2%	0%	0%	3%
Internal Medicine	\$9,804	2%	0%	1%	3%
Nuclear Medicine	\$53	-1%	-1%	-1%	-3%
Radiology	\$4,712	-1%	-1%	-2%	-3%
Vascular Surgery	\$1,098	0%	-3%	0%	-3%
Interventional Radiology	\$465	-1%	-3%	0%	-4%

Impact of Proposed Changes by Selected Specialties

*Note: Combined impact may not equal the sum of work, PE and malpractice as a result of rounding. Source: Table 138, CY 2023 Proposed PFS, display copy

This year, CMS provided an additional table that includes a facility/non-facility payment breakout of changes proposed for each specialty (Table 139).

CMS also seeks public comment on strategies to improve global surgical package valuation to support future rulemaking. Any change in the global period policy could impact specialties differently. Global surgical packages include the surgical procedure and services provided during pre- and postoperative visits. For the 2015 Medicare PFS final rule, CMS finalized a policy to transition all services with a 10-day and 90-day global period to 0-day global periods. Implementation of this policy was halted by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, which required CMS to collect additional data on how best to value global packages.





In the 2023 proposed rule, CMS states that it "continue[s] to be concerned that our current global packages reflect certain [evaluation and management](E/M) visits that are not typically furnished in the global period, and thus, are not occurring." CMS welcomes comments from the public on ideas for other sources of data that can help assess global package valuation.

Practice Expense

Key Takeaway: CMS will likely address indirect PEs in future rulemaking.

Beginning in 2019, CMS updated the supplies and equipment prices used for calculating PEs, which were implemented through a four-year transition that was finalized in 2022. Last year, CMS finalized a proposal to update prices for clinical labor through a four-year transition period that will be completed in 2025. Physician specialties with substantially higher average shares of direct costs attributable to clinical labor are anticipated to see increases in payment from the clinical labor pricing update, while those with lower average shares of direct costs attributable to labor are anticipated to see decreases in payment. During the four-year transition period, clinical labor rates will remain open for public comment.

Although CMS did not propose a methodology for updating future PEs, CMS believes "it is necessary to establish a roadmap toward more routine PE updates." CMS also believes that indirect PEs would benefit from a data refresh, and signals "[its] intent to move to a standardized and routine approach" to valuing indirect PEs. CMS seeks comments from the public on how to better refine its PE methodology, including the collection of better data, the cadence for future updates and how to appropriately value indirect PEs.

Rebasing and Revising the Medicare Economic Index

Key Takeaway: CMS proposes a new methodology for updating the Medicare Economic Index (MEI) for future years.

The MEI measures the input price pressures of providing physician services, looking at physicians' own time (compensation) and physicians' PE While the MEI is no longer directly used in calculating the annual update to the PFS CF, it continues to be used for the Medicare telehealth originating site facility fee, targeted medical review threshold amounts, Rural Health Clinic Payment Limits, geographic practice cost index and other policies. The current MEI relies on 2006 data for self-employed physicians and may not account for current costs and market changes.

In this rule, CMS proposes a new methodology to both rebase and revise the MEI that relies on publicly available data. CMS believes that the proposed new methodology would allow for the use of data that are more reflective of current market conditions of physician ownership practices, rather than only reflecting costs for self-employed physicians, and would allow the MEI to be updated on a more regular basis.

CMS notes that using the proposed new MEI cost weights to set PFS rates should not change overall spending on PFS services but would likely result in significant changes to payments among PFS services. Accordingly, the agency does not propose to use the updated MEI cost share weights to set payments for CY 2023 but asks for feedback on potential future use.

Split (or Shared) Services

Key Takeaway: CMS delays implementing "substantive portion" definition until January 1, 2024.

In the CY 2022 PFS final rule, CMS finalized a policy allowing reimbursement to a physician or non-





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physician practitioner (NPP) for shared (or split) visits when the billing practitioner performs a "substantive portion" of the services. CMS defined "substantive portion" as more than half of the total time spent on the service. CMS chose to phase in implementation of this definition and to allow the history, physical examination, medical decision making (MDM) or more than half of the total time spent with a patient to determine the "substantive portion" of the visit. Starting in 2023, the definition would be limited only to time spent with the patient, allowing the provider spending more than half of the total time to bill for these services.

In this rule, CMS proposes to delay implementation the new "substantive portion" definition to January 1, 2024. When CMS proposed this policy last year, it was controversial. CMS received feedback from stakeholders that the new definition focuses only on time spent, does not include MDM and may require changes to practice workflows to track time spent on visits. CMS maintains that the appropriate definition of "substantive portion" is more than half of the total time but will delay implementation to allow for enactment of other policies related to E/M codes and to provide providers time to prepare for the policy. Clinicians may continue to use history, physical examination, MDM or more than half of the total time spent with patient when defining "substantive portion" of split (or shared) services in 2023. CMS clarifies that the split (or shared) services policy excludes critical care visits.

Telehealth and Other Remote Services

Key Takeaway: CMS would maintain services added to telehealth list during the PHE, keep certain services until 151 days post-PHE and add several codes to Category 3.

During the COVID-19 PHE, the US Department of Health and Human Services (HHS) issued several waivers and flexibilities that made it easier to provide telehealth services to Medicare beneficiaries. In March 2022, Congress passed, and the president signed, an omnibus package that extended certain telehealth flexibilities related to the PHE for 151 days (approximately five months) after the PHE ends. These waivers, which are tied to the PHE, provide flexibility regarding the locations where telehealth can be provided (e.g., at home), which services can be provided, what type of technology can be used (and the level of payment for telehealth services (e.g., allowing the higher non-facility rate for office-based physicians). Use of telehealth services increased dramatically during the PHE. Providers, patients and other stakeholders are urging Congress and CMS to allow continued access to telehealth services by maintaining these flexibilities after the PHE ends.

In 2022, CMS finalized a temporary extension of telehealth coverage for certain services through CY 2023. This temporary extension will allow the agency to collect more data to inform the structure of telehealth coverage in a post-COVID-19 environment. As demand for telehealth has grown, CMS has prioritized efforts to determine which services can be appropriately provided via telehealth from a clinical perspective, and efforts to address fraud and abuse. The agency has also acknowledged that expanded telehealth policies may help address access disparities.

While stakeholders anticipated that CMS might extend coverage for certain telehealth services beyond CY 2023 in the PFS proposed rule, the agency did not do so. CMS noted that if the PHE remains in place well into CY 2023, the agency may revisit this policy. The agency also proposes to keep certain telehealth flexibilities (including telephone E/M services) that would have otherwise ended when the PHE ends for 151 days post-PHE to align with the provisions mentioned above in the omnibus package.

These proposals mean there are now two timeframes for codes to remain on the Medicare Telehealth Services List: 151 days post-PHE (Table 10 of CY 2023 PFS Proposed Rule) and the end of CY 2023. CMS acknowledges that the PHE may end before the CY 2023 PFS is finalized and therefore intends to issue program guidance and/or other sub-regulatory guidance to provide more certainty to stakeholders McDermott+



on a post-PHE transition.

Key telehealth proposals are outlined below.

Proposal	Details	
<u>Extension of Temporary</u> <u>Additions to Medicare</u> <u>Telehealth List Through 151</u> <u>days Post-PHE</u>	In the CY 2021 Final Rule, CMS provided coverage through the end of the PHE for more than 100 services added to the Medicare Telehealth List on an interim basis. Some services were added on a temporary interim basis, while others were given Category 3 status (Categories 1 and 2 represent the long- term criteria for additions to the telehealth list; Category 3 was created to allow additions not clearly fitting under Categories 1 and 2). Currently, Category 3 codes will remain on the list through the end of CY 2023.	
	interim basis (but not yet given Category 3 status) for 151 days post-PHE, to align with telehealth flexibilities included in the omnibus. These codes would be removed from the telehealth list when the PHE ends (Table 10 in CY 2023 PFS Proposed Rule).	
Codes Granted Category 3 Status	CMS proposes to grant more than 50 codes Category 3 status (Table 8 in CY 2023 PFS Proposed Rule).	
<u>Three Permanent Additions to</u> <u>Medicare Telehealth List</u>	CMS received many requests for Category 1 and 2 additions. While CMS denied most of these requests, the agency proposes to create three new Healthcare Common Procedure Code System (HCPCS) codes that would be added on a Category 1 basis (Table 10 in CY 2023 PFS Proposed Rule).	
<u>Delay of In-Person Requirement</u> <u>for Mental Health Services</u>	The proposed rule attempts to align the 151 post-PHE provision in the omnibus with the regulatory flexibilities that were to be effective at the end of the PHE.	
	CMS proposes to delay the in-person requirements for telehealth services furnished for purposes of diagnosis, evaluation or treatment of a mental health disorder until the 152nd day after the PHE ends.	
<u>Update of Telehealth Originating</u> Site Facility Fee	The proposed rule would apply the MEI increase of 3.7% for CY 2023.	
	CMS proposes to increase the telehealth originating site facility fee from \$27.59 to \$28.61.	





CMS is attempting to align the timeframes for the end of certain Medicare telehealth flexibilities. The agency's ability to do so remains limited, however. Congressional action is still necessary to remove existing barriers such as originating site and geographic restrictions. While CMS has taken steps to provide more clarity, stakeholders should continue to advocate for congressional action to extend these changes for more than 151 days, if not permanently.

<u>Key Takeaway: CMS proposes coding changes for remote treatment management (RTM)</u> <u>services and seeks additional information on RTM services furnished.</u>

In recent years, CMS has established payment for several remote physiologic monitoring (RPM) codes. These codes generated significant stakeholder interest even prior to the pandemic. During the PHE, CMS implemented flexibilities to allow broader use of these services but provided limited guidance on how they should be reported. Industry stakeholders expected a significant increase in use of these codes and anticipated that CMS might propose additional policies to further clarify and potentially limit the use of these codes. While utilization for some of the RPM codes again increased substantially from last year, CMS does not propose any policy changes specific to the RPM codes in this rule.

In last year's final rule, CMS introduced new RTM codes (98975–98981) that became effective January 1, 2022, and finalized payment rates for these new codes, similar to the RPM codes. CMS expressed concerns about a subset of the RTM codes and whether they could be billed (as intended) by a subset of practitioners (including physical and occupational therapists as well as speech language pathologists) outside the context of billing for incident-to services of a healthcare practitioner.

The first set of codes would allow for the general supervision of auxiliary personnel by physicians and non-physician practitioners. These codes would include the physician work and direct PE inputs similar to the existing treatment management codes.

Code	Descriptor
GRTM1	Remote therapeutic monitoring treatment management services, physician or NPP professional time over a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes of E/M services
GRTM2	Remote therapeutic monitoring treatment management services, physician or NPP professional time over a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes of E/M services during the calendar month (list separately in additional to code for primary procedure)

The second set of codes would allow for the furnishing of services by qualified nonphysician healthcare professionals who cannot bill services furnished incident to their professional services. The valuation of these codes would not contemplate the incident-to activities.



Code	Descriptor
CDTM2	Remote therapeutic monitoring treatment assessment services, first 20 minutes furnished personally/directly by a nonphysician qualified healthcare professional over a calendar month requiring at least one interactive communication with the patient/caregiver during the month
GRTM4	Remote therapeutic monitoring treatment assessment services; additional 20 minutes furnished personally/directly by a nonphysician qualified healthcare professional over a calendar month requiring at least one interactive communication with the patient/caregiver during the month (list separately in additional to code for primary procedure)

CMS received requests for a new device RTM code but did not choose to create an additional code in this proposed rule. Instead, CMS seeks stakeholder comments on the following details regarding RTM devices that are used to deliver services:

- Types of data collected using RTM devices
- Costs associated with RTM devices that are available to collect RTM data
- Potential number of beneficiaries for whom an RTM device might be used by the health condition type.

In this proposed rule, CMS also introduced the new RTM device code for cognitive behavioral therapy, 989X6 (Remote therapeutic monitoring (e.g., therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavior therapy, each 30 days)). Because the devices in this space are still emerging and evolving, the American Medical Association RVS Update Committee recommended that the code be contractor priced for CY 2023. CMS agreed with this position and proposed no national price for this code effective January 1, 2023.

Potentially Misvalued Codes

Key Takeaway: CMS solicits comments on potentially misvalued codes.

The Affordable Care Act mandates regular review of fee schedule rates for physician services paid by Medicare, including services that have experienced high growth rates. CMS established the potentially misvalued code process to meet this mandate. Table 6 in the CY 2023 proposed rule provides the codes for review, which cover a range of services, such as home visits and ophthalmological services, including cataracts. Codes identified for review under this process may eventually have their values increased, decreased or maintained. The risk of reduced values is often a concern for stakeholders when one of their services is proposed for revaluation under this process.

Quality Payment Program

Under the QPP, eligible clinicians elect to either be subject to payment adjustments based upon performance under MIPS or participate in the Advanced Alternative Payment Model (APM) track. Eligible clinicians choosing the MIPS pathway will have payments increased, maintained or decreased based on relative performance in four categories: Quality, Cost, Promoting Interoperability and Improvement Activities. Eligible clinicians choosing the APM pathway will automatically receive a bonus





payment once they meet the qualifications for that track. CMS will also implement a new alternative to traditional MIPS, the MVPs, as a voluntary option starting in 2023.

MIPS Value Pathways

Key Takeaway: CMS will initiate MVPs in 2023 with 12 proposed pathways.

The MVPs are a participation option to motivate clinicians to move away from reporting on selfselected activities and measures (traditional MIPS) and towards an aligned set of measure options designed to be meaningful to patient care, better connect measures across MIPS categories and be more relevant to a clinician's scope of practice. Over the years, participation in traditional MIPS has been criticized as expensive and time consuming with low positive payment adjustments as a reward, and as having an uncertain impact on patient care. At the same time, some stakeholders have raised concerns about sunsetting MIPS because the MVPs are untested, and it is unclear whether there will be MVP options for all participants. In the CY 2022 final rule, CMS finalized a proposal to launch the MVPs in 2023, set an implementation timeline and defined MVP criteria.

In this rule, CMS outlines the following MVP proposals:

MVP Implementation Timeline

CMS proposes to initiate the MVP program as a voluntary option, to provide time for MIPS eligible clinicians to familiarize themselves with MVPs and begin preparing their practices for participation (*e.g.*, via system updates):

- For the **2023**, **2024** and **2025** performance years, CMS proposes to allow individual clinicians, single specialty groups, multispecialty groups, subgroups and APM entities to report MVPs.
- For the **2026 performance year** and future years, CMS proposes to allow individual clinicians, single specialty groups, subgroups and APM entities to report MVPs. Beginning in the 2026 performance year, multispecialty groups will be required to form subgroups in order to report MVPs. Subgroups have additional detailed reporting and scoring requirements.
- In last year's PFS proposed rule, CMS proposed to move all clinicians to MVPs by 2027. However, CMS has not finalized a definitive end date for traditional MIPS and reiterates in this rule that such a determination has not been made.

MVP Criteria

Like MIPS, MVP have different categories:

- **Quality Performance.** MVP participants will select four quality measures. One must be an outcome measure (or a high-priority measure if an outcome isn't available or applicable).
- **Improvement Activities Performance.** MVP participants will select two mediumweighted improvement activities, one high-weighted improvement activity or participation in a patient-centered medical home.
- **Cost Performance.** MVP participants will be scored on the cost measures included in the MVP that they select and report.
- Foundational Layer:
 - Population Health Measures. At the time of MVP registration, participants will select one population health measure, and the results will be added to the quality score.
 - Promoting Interoperability Performance. MVP participants will report on the same

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Promoting Interoperability measures required under traditional MIPS, unless they qualify for reweighting.

New MVPs

CMS proposes five new MVPs that would be available beginning with the 2023 performance year:

- Advancing Cancer Care
- Optimal Care for Kidney Health
- Optimal Care for Patients with Episodic Neurological Conditions
- Supportive Care for Neurodegenerative Conditions
- Promoting Wellness.

CMS established seven MVPs in last year's final rule and offers refinements to each:

- Advancing Rheumatology Patient Care
- Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes
- Advancing Care for Heart Disease
- Optimizing Chronic Disease Management
- Adopting Best Practices and Promoting Patient Safety within Emergency Medicine
- Improving Care for Lower Extremity Joint Repair
- Patient Safety and Support of Positive Experiences with Anesthesia

MVP participants will not be able to submit or make changes to the MVP they select after the close of the registration period and will not be allowed to report on an MVP for which they did not register. CMS states that going forward it will broaden the opportunity for the public to provide feedback on MVP candidates and updates to existing MVPs.

<u>Scoring</u>

MVP scoring policies will generally align with those used in traditional MIPS across all performance categories, including polices regarding performance category weights.

Some stakeholders may raise concerns about whether MVPs are a sufficient departure from the current program and whether there will be MVP options for all participants and specialties. It will be interesting to observe which physicians and entities choose to move forward with the MVPs in 2023 and how fast the transition away from traditional MIPS occurs.

Merit-Based Incentive Payment System

Key Takeaway: CMS proposes to maintain the current program threshold to avoid a MIPS penalty.

To avoid a negative adjustment in the 2025 payment year, providers' MIPS total score must reach a performance threshold. CMS proposes to maintain the MIPS performance threshold for the 2023 performance year at 75 points, the same as the last performance year. The 2023 MIPS performance threshold was set using the mean score from the 2019 performance year. Historically, CMS has increased the MIPS performance threshold, making participation more challenging, and the agency noted that it could have proposed a threshold as high as 89 points. The agency could still change the threshold in the final rule and in future years as the program continues to develop.





Changes to MIPS Performance Categories and Weights

CMS proposes to update the measures in the various performance categories for the 2023 performance year:

- Quality 192 total measures proposed, including nine additions
- Cost addition of the Medicare Spending Per Beneficiary Clinician measure as a care episode group
- Improvement Activities addition of four new activities, modifications to five existing activities and removal of five activities
- Promoting Interoperability addition of a new Health Information Exchange Objective option and the Enabling Exchange under the Trusted Exchange Framework and Common Agreement (TEFCA) measure, with specific measures outlined in more detail in the QPP fact sheet.

CMS proposes to expand the definition of "high-priority measures" to include health-equity-related quality measures. CMS also states that for the CY 2022 performance period/2024 MIPS payment year, it plans to measure improvement for the cost performance category for the first time, with a maximum cost improvement score of 1 percentage point.

The MIPS performance category weights are summarized below. Since these are specified in statute, they are not open for comment and have not changed from the previous year.

Performance Category	PY 2022 Weight	PY 2023 Proposed Weight
Quality	30%	30%
Cost	30%	30%
Promoting Interoperability	25%	25%
Improvement Activities	15%	15%

CMS includes several requests for information (RFIs) related to the MIPS program. In keeping with the Biden Administration's focus on health equity, CMS seeks feedback on developing and implementing health equity measures for the MIPS quality performance category. The RFIs also seek comments on how to incorporate technological advancements into the quality reporting program, including moving to digital quality measures (last year's rule included a similar RFI) and leveraging TEFCA to improve submission of clinical documentation to support claims adjudication and prior authorization processes.

In recent years, participation in MIPS has decreased because of COVID-19-related exemptions. As the end of the PHE potentially approaches, it remains to be seen whether this trend will have any long-term impact on the program.

Advanced APM Track

Key Takeaway: The Advanced APM incentive payment expires at the end of 2022.

MACRA included a 5% incentive payment for clinicians participating in advanced APMs through the 2022 performance year/2024 payment year. Absent congressional action, those payments are set to expire this year. Stakeholders are actively working to secure an extension in an end-of-year package.

In performance year 2024/payment year 2026, MACRA provides for two different CFs depending on





advanced APM participation. Eligible clinicians who are qualifying participants in advanced APMs will receive a differentially higher 0.75% update to the CF compared to the 0.25% update to the general CF each year.

In the proposed rule, CMS notes its concern that the structure of the MACRA payment system could result in higher payments through MIPS in absence of the advanced APM bonuses, even accounting for the CF differential. CMS states that this could shift clinicians into MIPS and out of advanced APMs. CMS seeks feedback through an RFI on whether administrative action is needed to address these challenges beginning in CY 2024.

Medicare Shared Savings Program

Key Takeaway: CMS proposes new advanced investment payments to certain ACOs.

In October 2021, the CMS Innovation Center announced its refreshed strategy, including a new objective that all Medicare beneficiaries be in a care relationship with accountability for quality and total cost of care by 2030, and a second objective advancing health equity. In this rule, CMS proposes policy changes aimed at bolstering these goals. CMS proposes to create an option for Advance Investment Payments (AIP) to certain ACOs, intended to increase participation in accountable care models in underserved communities. This proposal builds on the success of the ACO Investment Model (an Innovation Center model that tested the effects of advanced payments to certain ACOs participating in the MSSP) and would allow low-revenue ACOs that are inexperienced with performance-based risk and are new to the MSSP to receive advanced payment of their shared savings for the first two years of an ACO's five-year agreement period. AIPs would include a one-time fixed payment of \$250,000 and quarterly payments based on risk factors for the beneficiary population, capped at 10,000 assigned beneficiaries. Previous experiments with pre-payment have shown an increase adoption of accountable care in underserved communities. The proposed rule lays out proposed criteria for participation, calculating the payment amount, use of the pre-paid funds, repayment and other details of the new option. Many stakeholders have called for a pre-payment option to assist with upfront investment costs associated with starting an ACO.

Key Takeaway: CMS proposes changes to the MSSP intended to drive participation.

CMS proposes numerous changes to the MSSP intended to increase participation and address stakeholder concerns about benchmarking accuracy. These changes include the following:

- Allowing inexperienced ACOs to participate in the MSSP in upside-only shared savings for seven years before transitioning to two-sided risk (one five-year agreement under BASIC level A and a second agreement with the BASIC level glidepath, allowing two years under one-sided risk)
- Removing the limitation on the number of agreement periods in which an ACO can participate in BASIC Level E, and making participation in BASIC Level E optional
- Implementing a combination of benchmarking policies that would incorporate a prospective, external factor into the methodology for updating historical benchmarks; incorporate a prior savings adjustment; and reduce the impact of the negative regional adjustment
- Modifying the risk adjustment methodology to account for medically complex, high cost beneficiaries while continuing to address the agency's concerns about coding practices
- Using a sliding scale approach to ACO eligibility for shared savings based on quality performance (as opposed to the current cliff-like approach where ACOs that do not meet established thresholds





do not share in any savings)

- Extending the incentive for reporting electronic clinical quality measures (eCQMs)/MIPS CQMs through PY 2024 to align with sunsetting of the CMS Web Interface reporting option
- Implementing a health equity adjustment of up to 10 bonus points for an ACO's MIPS quality performance category score when reporting all-payer eCQMs/MIPS CQMs based on quality performance and providing care to a higher proportion of underserved or duals
- Reducing administrative burden for ACOs by removing requirements around CMS review of marketing materials and modifying requirements for beneficiary notice; removing the requirement that ACOs apply for the skilled nursing facility three-day rule waiver and replacing it with an attestation; and updating data sharing regulations
- Revising the definition of primary care services used for beneficiary alignment to incorporate new prolonged service codes and new chronic pain management (CPM) codes.

CMS also seeks comments on two potential social determinants of health measures, the addition of new CAHPS for MIPS survey questions, and an alternative approach to calculating ACO historical benchmarks using administratively set benchmarks (in line with recent discussions by MedPAC and others).

Changes that afford some types of participants additional time in upside-only arrangements may increase participation in the MSSP, consistent with the administration's goals. The changes to benchmarking and risk adjustment will need to be modeled to determine whether they meet stakeholder needs.

Requests for Information

Health Equity Initiative

Key Takeaway: CMS solicits comments on the potential inclusion of two new social drivers of health screening measures in the APM performance pathway measure set.

The Biden Administration released the <u>Executive Order on Advancing Racial Equity and Support for</u> <u>Underserved Communities Through the Federal Government</u> on January 20, 2021, and directed agency leadership to review, manage and establish policy using an equity lens. In response, HHS has advanced health equity through many RFIs, policies and actions.

In the CY 2023 PFS proposed rule, CMS maintains its focus on health equity by assessing the quality performance of MSSP, and through several other proposals. CMS seeks feedback on the potential inclusion of two new measures in the APM performance pathway measure set:

- Screening for social drivers of health
- Screen positive rate for social drivers of health.

CMS seeks comments on the value of these measures, how to implement them, what barriers might impede implementation, what flexibilities CMS should consider when implementing the measures, and what impact these measures will have on providing care to underserved populations.

CMS previously received comments expressing the following:

- Support for the stratification of data and quality measures by social risk factors
- Concern that the CQMs would divert resources into electronic systems instead of focusing on health equity





• Advocacy for changing the MSSP payment structure to allow for the development of infrastructure that addresses health equity.

Principles for Measuring Healthcare Quality Disparities

The proposed rule includes an RFI on issues that CMS should consider when advancing measurement and stratification as tools to address healthcare disparities and improve healthcare equity. The RFI includes five areas that could inform the agency's approach:

- Goals and approaches for measuring healthcare disparities and using measure stratification across CMS quality programs
- Guiding principles for selecting and prioritizing measures for disparity reporting across CMS quality programs
- Principles for social risk factor and demographic data selection and use
- Identification of meaningful performance differences
- Guiding principles for reporting disparity results.

CMS also seeks comment on additional disparity measurement or stratification guidelines suitable for overarching consideration across quality programs.

Other Proposals

Behavioral Health

Key Takeaway: CMS proposes efforts to expand access to, and address shortages of, behavioral services and health providers.

Efforts to address behavioral health have gained momentum, especially in the wake of the COVID-19 pandemic and significant gun violence events. While Congress considers several mental health bills, regulators are working to expand access to behavioral health services for Medicare beneficiaries. CMS proposes two policies to achieve this objective:

- To allow licensed professional counselors and licensed marriage and family therapists to bill Medicare under general supervision
- To create a new code (GBHI1) for general behavioral health integration services to be performed by clinical psychologists (CPs) and clinical social workers (CSWs) when they are the focal point of integration.

CMS proposes to crosswalk GBHI1 to 99484 with a work value of 0.61 because the agency believes services under GBHI1 mirror those under 99484. To support use of the new code, CMS proposes to allow the psychiatric diagnostic evaluation CPT code 90791 to serve as the initiating behavioral health visit, which is required for all behavioral health integration services. Currently, no CPT codes are eligible to be used for the initiating visit requirement.

CMS solicits comments on the proposed work value, whether additional coding is needed (*e.g.*, separate CP and CSW codes), the proposed billing requirements (*e.g.*, "incident to"), the role and responsibilities of CPs and CSWs, and whether additional codes should be permitted to qualify for the initiating visit



requirement.



Key Takeaway: CMS proposes to create two codes for CPM services.

CMS proposes to create the following two codes for CPM services effective January 1, 2023.

Code	Description
GYYY1	Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care (e.g. physical therapy and occupational therapy, and community based care), as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health care professional, per calendar month. (When using GYYY1, 30 minutes must be met or exceeded.)
GYYY2	Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month (List separately in addition to code for GYYY1). (When using GYYY2, 15 minutes must be met or exceeded.)

CMS does not believe that existing E/M codes appropriately represent the resources and services required to perform CPM services and asserts its authority to establish the new codes. CMS proposes to crosswalk GYYY1 to the work RVU (1.45) and PE of principal care management code 99424, given the similar services of "care plan, medication management, unusually complex clinical management; care coordination between relevant practitioners furnishing care; and time for care provided personally by a physician or other qualified health care professional." Similarly, CMS proposes to crosswalk GYYY2 to principal care management code 99425 with half the work RVU (proposed at 0.50) and half the PE values, based on the comparable services.

With these new codes, CMS expects to collect data on the prevalence and impact of chronic pain on Medicare beneficiaries that will assist the agency with future valuation adjustments. CMS will consider adding the codes to the Medicare Telehealth Services after reviewing comments and analyzing how these new services may be provided to Medicare beneficiaries.

Refunds with Respect to Discarded Amounts of Single-Dose or Single-Use Package Drugs

Key Takeaway: CMS proposes to make determinations on manufacturer refunds for discarded amounts of single-dose container or single-use package drugs.

Section 90004 of the Infrastructure Investment and Jobs Act, signed into law on November 15, 2021, requires manufacturers to provide a refund to CMS for certain discarded amounts from single-dose container or single-use package drugs. CMS presents various proposals to implement this statutory requirement. CMS proposes that hospital outpatient departments and ambulatory surgery centers be required to report the JW billing modifier to determine the total number of billing units of the HCPCS code





of a refundable drug, with a few exceptions. CMS also proposes to require the establishment and use of a JZ billing modifier for providers to indicate that no amount of the drug was discarded.

These proposals would be applicable to Medicare Part B drugs described as "single-dose" or "single-use" within the US Food and Drug Administration approved label. CMS proposes to exclude radiopharmaceuticals and imaging agents, as well as drugs requiring filtration, from these requirements. CMS also proposes to exclude drugs for which payment under Medicare Part B has been made for fewer than 18 months (using the first day of the quarter following the date of first sale of the drug reported to CMS).

CMS proposes to send manufacturers annual reports containing data and calculated refund amounts, and to require manufacturers to pay refunds on an annual basis. The refund amount would be equal to the amount by which the product of (1) the total number of units of drug discarded and (2) the Medicare payment limit of the drug exceeds 10% of the drug's total allowed charges (*i.e.*, the amount Medicare paid) during the quarter. CMS also proposes a dispute resolution process and civil monetary penalty for failure to comply.

Average Sales Price for Certain Self-Administered Drug Products

Key Takeaway: CMS proposes to implements regulations to control the price impact of selfadministered drugs on Medicare Part B payments.

Drugs eligible for payment under Medicare Part B are generally reimbursed based on a statutory formula of 106% of the drug's average sales price (ASP) (not accounting for any effects of sequestration). Generally, drugs reimbursed under Medicare Part B are not self-administered drugs. However, multiple formulations of a drug assigned different national drug codes may have prices crosswalked to an HCPCS code to which a price is assigned.

When one or more of the formulations of a drug crosswalked to an HCPCS code are marketed as selfadministered, the price of the self-administered drug that is not reimbursed by Medicare Part B (which may be covered by Medicare Part D prescription drug plans) can impact the price of the drug under Medicare Part B. This could result in a provider or supplier being paid substantially more than 106% of the drug's cost.

The <u>Office of Inspector General (OIG) raised concerns</u> that this situation could provide perverse economic incentives. The omnibus legislation of 2021 directed the OIG to look for such drugs, report them to HHS, and permit Medicare to make a payment rate determination that includes or excludes self-administered drug price data, based on whichever calculation provides the lower price. CMS implemented this authority in the CY 2022 PFS.

Earlier this year, HHS Secretary Becerra instructed CMS to reassess the 2022 Part B premium amount in response to a price reduction for the drug Aduhelm[™], used in treating Alzheimer's disease. The 2023 premium is expected to be lower than the 2022 premium. The final determination will be made later this fall.



Clinical Laboratory Fee Schedule

Key Takeaway: CMS proposes conforming changes to the Protecting Access to Medicare Act of 2014 (PAMA) data reporting and payment requirements.

CMS proposes to make conforming changes to reflect the most recent changes to the PAMA data reporting requirements and payment requirements. In December 2021, Congress passed the Protecting Medicare and American Farmers from Sequester Cuts Act that further delayed the data reporting timeline for data collected in Q1 and Q2 2019. That law established the data collection period as January 1, 2023, through March 31, 2023, for rates that would become effective January 1, 2024. The law also stated that clinical laboratory fee schedule rates may not be reduced between 2021 and 2022, and that payment rates in CYs 2023–2025 may not drop by more than 15% each year when compared to the preceding year.

In this rule, CMS proposes to make the necessary conforming changes to reflect the current requirements. The agency does not propose any changes to the data collection period, the data reported in said collection period, or the limit on the payment rate changes in the upcoming calendar years.

Key Takeaway: CMS proposes to codify and clarify its specimen collection and travel allowance policies.

Section 1833(h)(3)(a) of the Social Security Act allows for the payment of a nominal fee for specimen collection for laboratory testing performed on a Medicare patient and paid under Medicare Part B. In this rule, CMS proposes to codify its existing specimen collection policies, while excluding language for policies that no longer apply. CMS proposes to codify a specimen collection fee of \$3 for all specimens collected in a single encounter. A nominal increase in the specimen collection fee would only apply where the lab collected the specimen on behalf of a home health agency or from a patient in a skilled nursing facility. CMS also proposes that the fee would apply to only two types of specimen collection for which HCPCS codes exist: blood collected through venipuncture and urine sample by catheterization. CMS does not propose to extend the specimen collection fee for COVID-19 clinical diagnostic laboratory tests beyond the end of the PHE.

Section 1833(h)(3)(b) of the Social Security Act allows for the payment of a travel allowance fee to cover the transportation expenses of trained personnel traveling to a location to collect a specimen from a Medicare beneficiary. In response to questions received during the pandemic regarding travel allowance policies, CMS proposed to codify its policies in order to bring more clarity.

While CMS proposes codification of existing policies, the agency seeks comment on all aspects of its travel allowance proposal as outlined in the proposed rule.

Appropriate Use Criteria Program

Key Takeaway: CMS delays the penalty phase of the Appropriate Use Criteria (AUC) program for an indeterminate period of time.

Section 218(b) of PAMA established the AUC program, under which a practitioner who orders an advanced diagnostic imaging service for a Medicare beneficiary in an applicable setting is required to consult an AUC using a qualified clinical decision support mechanism. The practitioner furnishing the imaging service must report the AUC consultation information on the Medicare claim.





Consulting

In the CY 2018 rulemaking cycle, CMS established January 1, 2020, as the AUC program's effective date, with the first year serving as the operations and education testing period. In July 2020, in response to the COVID-19 PHE, CMS extended the testing period an additional year. In the CY 2022 PFS final rule, CMS finalized its policy to delay the payment penalty phase of the AUC program until January 1, 2023, at the earliest.

While the CY 2023 PFS proposed rule itself does not include any changes to the AUC program, CMS announced a further delay to the penalty phase of the program in conjunction with the release of the proposed rule. CMS stated on the AUC program website that the educational and testing program would continue until further notice, and that the penalty phase would not begin on January 1, 2023, even if the PHE ends in CY 2022.

Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers

Key Takeaway: CMS proposes two updates to expand Medicare coverage policies for colorectal cancer screening

CMS proposes to expand Medicare coverage for certain colorectal cancer (CRC) screening tests by reducing the minimum age payment limitation from 50 years to 45 years. In May 2021, the US Preventive Services Task Force (USPSTF) issued a revised recommendation (with a Grade B) regarding a similar policy. CMS also proposes to expand coverage for barium enema tests and blood-based biomarker tests to a minimum age of 45, even though that change was not included in the USPSTF recommendation. CMS otherwise retains the existing frequency limitations.

CMS also proses to expand the regulatory definition of CRC screening tests to include a follow-on screening colonoscopy after a positive result from a Medicare covered non-invasive stool-based CRC screening test. Currently, a colonoscopy after a positive result from a CRC screening stool-based test is considered "diagnostic" or a treatment/management of the medical problem. CMS proposes that effective January 1, 2023, CRC screening tests will include follow-on screening colonoscopies after a Medicarecovered non-invasive stool-based colorectal cancer screening test returns a positive result. Therefore, the beneficiary cost sharing would not be applicable for the stool-based test or the follow-up colonoscopy.

Other Policies Addressed by the Proposed Rule

The CY 2023 rule includes several other proposals, including the following:

- Payment for dental examinations and dental treatment preceding an organ transplant
- Updates to preventative vaccine administration payment, including for COVID-19 vaccines.

The CY 2023 PFS proposed rule outlines important physician payment and quality proposals for 2023, but great uncertainty remains about final Medicare reimbursement rates. Stakeholders will likely again turn to Congress to seek mitigation of overall physician payment cuts, but congressional action on these issues is unlikely before the end of the year, especially in light of the upcoming elections. Lawmakers' appetite to continuously patch physician payments is also unclear. While stakeholders are urging Congress to address cuts in 2023, there are also calls for Congress to find a more permanent solution to avoid the annual cuts to physician payment. Other policies in this rule set up significant changes for 2023 and beyond, including potential changes to participation in ACOs and the MVPs.

For more information, contact Haile Dagne, Deborah Godes, Marie Knoll, Mara McDermott, Kristen O'Brien, Jennifer Ohn or Devin Stone.

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