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# Regulatory Update: Medicare and Medicaid Programs; CY 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

**July 28, 2022**

## Background & Summary

On Thursday, July 7, the Centers for Medicare & Medicaid Services (CMS) issued the annual proposed rule to update the Calendar Year (CY) 2023 Medicare payment and policies for the Physician Fee Schedule (PFS) (hereinafter, "Proposed Rule"). The Proposed Rule revises payment polices under the Medicare PFS and makes other policy changes, including rebasing and revising the Medicare Economic Index (MEI), delaying split (or shared) billing requirements until CY 2024, changing certain evaluation and management (E/M) visits, and implementing telehealth provisions in the Consolidated Appropriations Act, 2022 to extend COVID-19 public health emergency (PHE) flexibilities. The PFS Addenda, along with supporting documents and tables referenced in the Proposed Rule, are available on the CMS website. The Proposed Rule also includes changes to the Quality Payment Program (QPP) and several significant changes to the Medicare Shared Savings Program (MSSP).

Comments are due **September 6, 2022**, with effective dates for most sections scheduled for January 1, 2023. Vizient looks forward to working with members to help inform our comments to the agency.

## Calculation of the Proposed CY 2023 PFS Conversion Factor

There are three components that must be considered to value each service under the PFS – work, practice expense (PE), and malpractice (MP) relative value units (RVUs). Each component is adjusted by geographic cost indices (GPCIs), which reflect variations in the costs of furnishing services compared to the national average cost for each component. Then, the RVUs are converted to dollar amounts via the application of a conversion factor (CF), which is calculated by CMS's Office of the Actuary (OACT). Finally, the Medicare PFS payment amount (based on the below formula) for a given service and fee schedule area is calculated based on the previously discussed metrics.

PFS Payment= [(WorkRVU x WorkGPCI) + (PERVU x PEGPCI) + (MPRVU x MPGPCI)] x CF

For CY 2023, CMS proposes to decrease the CF by 1.55 percent to maintain budget neutrality. However, as described in Table 1, the proposed 2023 CF is $33.0775, which is a decrease of $1.5287 from the 2022 CF of $34.6062, or a 4.41742 percent decrease. This decline is in part driven by the expiration of a 3 percent payment boost provided in the CY 2022 Protecting Medicare and American Farmers from Sequester Cuts Act. Table 138 of the Proposed Rule (pgs. 1440-1441) shows the payment impact of the proposed policies by specialty and Table 139 (pgs. 1442-1446) distinguishes this impact by facility and non-facility setting.

| Calculation of the Proposed CY 2023 PFS Conversion Factor | | |
|---|---|---|
| **CY 2022 Conversion Factor** | | **34.6062** |
| Conversion Factor without CY 2022 Protecting Medicare and American Farmers from Sequester Cuts Act | | **33.5983** |
| Statutory Update Factor | 0.00 percent (1.0000) | |
| CY 2022 RVU Budget Neutrality Adjustment | -1.55 percent (0.9845) | |
| **CY 2023 Conversion Factor** | | **33.0775** |

**Table 1.**

While CMS proposes to rebase and revise the Medicare Economic Index (MEI), as described below, it was not used for purposes of CY 2023 ratesetting. According to CMS, implementing the MEI would have significant impacts on PFS ratesetting if implemented immediately, and therefore, CMS seeks additional feedback before the agency incorporates the updated MEI into PFS ratesetting. CMS clarifies it is similarly delaying implementation of the proposed rebased and revised MEI for use in the PE GPCI and also requests comments regarding appropriate timing for implementation.

More information regarding the Proposed PFS relative values can be found in the PFS Relative Value Files on the CMS website.

## Work Relative Value Units

The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the service. To establish the work RVU, CMS reviews the American Medical Association's Resource-Based Relative Value Scale Update Committee (RUC)-recommended work RVUs, intensity time and other components of the service that contribute to the value. Based on this information, CMS develops proposed values for specific codes. Addendum B on the CMS website includes additional information about the proposed work RVUs. In addition, in the Proposed Rule, CMS provides an analysis regarding its review of work RVUs, including where the agency's proposals differ from the RUC-recommended work RVUs.

## Malpractice Relative Value Units

Effective CY 2020, CMS's policy is to review, and if necessary, update the MP RVUs at least every three years. When updating MP RVUs for individual services, CMS considers: (1) specialty-level risk factors derived from data on specialty-specific MP premiums incurred by practitioners; (2) service-level risk factors derived from Medicare claims data of the weighted average risk factors of the specialties that furnish each service; and (3) an intensity/complexity of service adjustment to the service-level risk factor based on either the higher of the work RVU or clinical labor portion of the direct PE RVU.

In the Proposed Rule, CMS outlines the data sources used to calculate updated MP RVUs: MP premium data presumed to be in effect as of December 31, 2020; CY 2020 Medicare payment and utilization data; Higher of the CY 2022 final work RVUs or the clinical labor portion of the direct PE RVUs; and CY 2022 MP GPCIs. In addition, CMS outlines various methodological steps in the Proposed Rule. The MP RVUs are also shown in Addendum B on the CMS website.

## Practice Expense Relative Value Units

The Practice Expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding MP expenses. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expenses and all other expenses. PE RVUs are developed considering the direct and indirect practice resources involved in furnishing a service.

CMS allocates indirect costs at the code level based on the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. In addition, CMS incorporates survey data to determine indirect PEs incurred per hour worked (PE/HR) in developing the indirect portion of the PE RVUs.

### Clinical Labor Pricing

In the CY 2022 PFS final rule, CMS finalized a four-year, phased-in policy to update clinical labor pricing for CYs 2022 – 2025. Table 4 (pg. 40) of the Proposed Rule provides an example of the clinical labor pricing transition schedule and Table 5 (pg. 41-41) of the Proposed Rule provides the CY 2023 clinical labor pricing, most of which was finalized in the CY 2022 PFS final rule. CMS welcomes additional feedback regarding clinical labor pricing, including any data that will continue to improve the accuracy of the agency's final pricing.

Also, CMS notes that PE inputs used in setting PFS rates are often set by relying on historical survey data (almost all of which is over a decade old), some publicly available data collected for other purposes (for example, Bureau of Labor Statistics (BLS) wage data), recommendations from the American Medical Association and other provider groups, and annual Medicare claims data. To improve the information CMS uses in its PE methodology, CMS provides a general comment solicitation to identify how to improve the collection of PE data inputs and refine the PE methodology. In addition, CMS notes that it has contracted with RAND to develop and assess potential improvements in the current methodology used to allocate indirect practice costs in determining PE RVUs for a service, model alternative methodologies for determining PE RVUs, and identify and assess alternative data sources that CMS could use to regularly update indirect practice cost estimates. Further, CMS highlights the agency's intent to move to a standardized and routine approach to valuation of indirect PE and welcomes stakeholder feedback. In the Proposed Rule (pg. 46-48), CMS provides specific questions for stakeholder input but indicates a new approach to valuation of indirect PE would be addressed in future rulemaking.

### Changes to Health Care Delivery and Practice Ownership Structures, and Business Relationships Among Clinicians and Health Care Organizations

In the Proposed Rule, CMS notes that market consolidation, shifts in workforce alignment and other factors have suggested a significant transformation in the composition and proportions of practice expenses required to furnish case. Therefore, CMS seeks comment on evolving trends in health care business arrangements, use of technology, or similar topics that might factor into indirect PE calculations. CMS is interested in learning whether any PE data inputs may be obsolete, unnecessary, or misrepresentative of the actual costs involved in operating a medical practice. Also, regarding such trends, CMS indicates the agency is especially interested in issues related to beneficiary access to care, program integrity or quality issues that could arise, along with possible health equity impacts.

## Soliciting Public Comment on Strategies for Improving Global Surgical Package Valuation

To prepare for future rulemaking, CMS seeks comment on strategies to improve the accuracy of payment for the global surgical packages under the PFS. Global packages (i.e., 0-day, 10-day and 90-day) include the surgical procedure and any services typically provided during the pre- and post-operative periods (including evaluation and management (E/M) services and hospital discharge services). In the Proposed Rule, CMS references several RAND reports (available here) which analyzed claims data to review the services provided for each type of global package. CMS notes that RAND's analyses found that the reported number of E/M visits matched the expected number (included for purposes of PFS valuation) for only 4 percent of reviewed 10-day global packages and 38 percent of reviewed 90-day global packages. In addition, RAND modeled how valuation for global packages would change by adjusting the work RVUs, physician time, and direct PE inputs to reflect the observed number of E/M visits.

CMS notes that while there have been challenges to RAND's reports, it has not yet received data suggesting that postoperative E/M visits are being performed more frequently than indicated by the data in the RAND reports. CMS continues to have concerns regarding the current valuations of the global packages reflecting certain E/M visits that are not typically furnished in the global period, and as a result, CMS believes the visits are not occurring. CMS welcomes any comments from the public for other sources of data that would help to assess global package valuation (including the typical number and level of E/M services).

Also, CMS believes that changes to health care delivery may impact proper valuation of global services. CMS solicits comment on whether changes to health care delivery, including changes in coordination of care and use of medical technology over the past 3 decades, as well as during the recent PHE, have impacted: the number and level of postoperative E/M visits needed to provide effective follow-up care to patients; the timing of when postoperative care is being provided; and who is providing the follow-up care.

CMS also requests feedback on factors that could affect the ways postoperative E/M care is provided and whether, or how, recent changes in the coding and valuation of separately billable E/M services may have impacted global packages, among other questions. More generally, CMS reiterates its interest in feedback regarding whether global packages are misvalued, and if so, what would be an appropriate approach to valuation.

## Chronic Pain Management and Treatment (CPM) Bundles (HCPCS GYYY1 and GYYY2)

In the CY 2022 PFS proposed rule, CMS requested stakeholder input regarding refinements to the PFS to appropriately value chronic pain management and treatment (CPM) and in the final rule, indicated it would consider feedback in future rulemaking. In this year's Proposed Rule, CMS provides an overview of stakeholder comments and notes the agency's agreement with commenters who indicated that E/M codes may not reflect all the services and resources required to furnish comprehensive, chronic pain management to beneficiaries living with pain. CMS now proposes to create separate coding and payment for CPM services beginning January 1, 2023. Specifically, CMS proposes to create two HCPCS G codes (GYYY1[1] and

[1] HCPCS code 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

GYYY2[2]) to describe CPM services. CMS requests feedback regarding the need to include "administration of a validated pain assessment rating scale or tool," as an element of the proposed CPM services. Also, CMS requests comment on whether a list of such tools would be helpful in delivering CPM services and how the initial visit and subsequent visit should be conducted (e.g., in-person, via telehealth, or the use of a telecommunications system).

### Medicare Potentially Underutilized Services – Request for Information (RFI)

In the Proposed Rule, CMS requests comments on ways to identify high value services and how to recognize possible barriers to such high value, potentially underutilized services by Medicare beneficiaries. CMS also seeks comment regarding how it might best mitigate some of these obstacles (e.g., examining conditions of payment, payment rates, or prioritizing beneficiary and provider education investments).

In addition, the agency seeks comment on how best to define high value, potentially underutilized health services. Examples of high value services CMS is considering in a definition of high value service include preventive services, annual wellness visits, diabetes management training, screening for diabetes, referral to appropriate education/training services, immunizations/vaccines, cancer screenings, and more. CMS notes responses to the RFI may be used to identify potential opportunities for improvement of existing Medicare fee-for-service and Medicare Advantage programs.

### Comment Solicitation on Intensive Outpatient Mental Health Treatment, including Substance Use Disorder (SUD) Treatment, Furnished by Intensive Outpatient Programs (IOPs)

CMS seeks comment regarding whether the current coding and payment mechanisms under the PFS adequately account for intensive outpatient services that are part of a continuum of care. In addition, among other requests, the agency is interested in learning whether there is a gap in coding under the PFS or other Medicare payment systems that may be limiting access to needed levels of care for treatment of mental health or substance use disorder treatment, including SUDs for Medicare beneficiaries.

### Comment Solicitation on Payment for Behavioral Health Services under the PFS

CMS notes that the PFS ratesetting methodology and application of budget neutrality may impact certain services more significantly than others based on factors such as how frequently codes are revalued and the ratio of physician work to PE. CMS solicits comment on how it can best ensure beneficiary access to behavioral health services, including any potential adjustments to the PFS ratesetting methodology to systematically address the impact on behavioral health services paid under the PFS.

## Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

Several conditions, such as patient eligibility, originating sites, distant site practitioners and communications methods, must be considered before Medicare will make payments for

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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 professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using GYYY1, 30 minutes must be met or exceeded.).

[2] HCPCS code 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.).

telehealth services under the PFS. Other services involving communications technology (e.g., remote evaluation of recorded video and/or images submitted by an established patient, brief communication technology-based service (CTBS), online assessment and management) are also covered under the PFS but are different from telehealth services.

In the Proposed Rule, CMS proposes several changes related to telehealth services and implements recent law to extend various telehealth flexibilities that have been provided due to the COVID-19 public health emergency (PHE).

### Medicare Telehealth Service List

CMS maintains a Medicare telehealth services list[3] and has a long-standing process for adding or deleting services from the list. CMS notes that it received several requests, as provided in Table 7 of the Proposed Rule (pgs. 81-83), to permanently add various services to the Medicare Telehealth Services List effective for CY 2023. However, none of the requests that were received by the February 10, 2022, submission deadline met the agency's Category 1 or Category 2 criteria for permanent addition to the Medicare Telehealth Services List. However, CMS considered these services for Category 3, and proposes to add some services to Category 3, as shown in Table 8 of the Proposed Rule (pg. 101).

Table 9 of the Proposed Rule (pg. 101) lists services proposed for permanent addition to the Medicare Telehealth Services list on a Category 1 basis. Notably, CMS proposes to create new HCPCS codes to describe prolonged services associated with certain types of E/M services (GXXX1,[4] GXXX2,[5] and GXXX3[6]) and would be replacing existing codes that describe prolonged services.

Category 3 services are temporary services that CMS is considering for permanent inclusion. In the Proposed Rule, CMS reiterates that Category 3 services will continue to be covered through the end of 2023, however, should the PHE extend well into 2023, the agency may consider revisiting this policy.

### Services Proposed for Removal from the Medicare Telehealth Services List 151 Days Following the End of the PHE

The Consolidated Appropriations Act, 2022 (CAA, 2022), extends certain flexibilities implemented during the COVID-19 PHE. Specifically, the law provides geographic and originating site flexibility starting after the PHE ends for 151 days, as described below, for services on the Medicare Telehealth Services List as of March 15, 2022. In the Proposed Rule, CMS aims to implement this change and Table 10 of the Proposed Rule (pg. 104) lists those services that CMS proposes to retain on the Medicare Telehealth Services List for an

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[3] The Medicare Telehealth Services List currently consists of three categories. Category 1: Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare Telehealth Services List; Category 2: Services that are not similar to those on the current Medicare Telehealth Services List; and Category 3: Services added on a temporary basis that will ultimately need to meet the criteria under Category 1 or 2 in order to be permanently added to the Medicare Telehealth Services List. To add a specific service on a Category 3 basis, CMS conduced a clinical assessment to identify those services for which CMS could foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth.

[4] GXXX1 Prolonged hospital inpatient or observation care evaluation and management service(s) beyond the total time for the service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact.

[5] GXXX2 Prolonged nursing facility evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact.

[6] GXXX3 Prolonged home or residence evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact.

additional 151 days following the end of the PHE. CMS makes clear that on the 152nd day after the expiration of the PHE, payment for such services will again be limited.

### *Geographic Restrictions and Originating Site*

The CAA, 2022, permits telehealth services to be provided at any site in the United States where the beneficiary is located at the time of the telehealth service, including the individual's home, for 151 days after the end of the COVID-19 PHE. In addition, the CAA, 2022, provided similar flexibilities for the same 151-day period for telehealth services furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder and to individuals with a substance use disorder (SUD) diagnosis for purposes of treatment of the SUD or a co-occurring mental health disorder for the 151-days post-PHE. Further, a facility fee payment for these mental health or SUD telehealth services furnished during the 151-day period may be provided if certain geographic requirements are met[7] and the setting is on an enumerated list[8] (other than the patient's home).

In the Proposed Rule, CMS notes that the facility fee is updated based on the MEI and proposed an MEI increase of 3.7 percent for CY 2023. For CY 2023, the proposed payment amount for HCPCS code Q3014 (*Telehealth originating site facility fee)* is $28.61 (in CY 2022 the facility fee was $27.59). CMS indicates the final Medicare telehealth originating site facility fee will be revised for the final rule based on historical data and the most recently available total factor productivity.

### *Eligible Practitioners*

The CAA, 2022, also expanded the definition of eligible telehealth practitioners for the 151-day period to include quality occupational therapists, qualified physical therapists, qualified speech-language pathologists, and qualified audiologists.

### *Federally Qualified Health Centers (FQHC) and Rural Health Centers (RHCs)*

The CAA, 2022, continues payment for telehealth services for FQHCs and RHCs for 151-days after the PHE. Payment rates for FQHCs and RHCs, by statute, are similar to the national average payment rates for comparable telehealth services under the PFS.

### *Delay of the In-person Visit Requirement*

For mental health telehealth services, the CAA, 2021, required an in-person visit with the physician or practitioner within 6 months prior to the initial mental health telehealth service, and again at subsequent intervals as the Secretary determines appropriate. However, the CAA, 2022 delayed this requirement for 151 days after the PHE. CMS proposes regulatory changes to delay implementation of the in-person requirements, including when such mental health services are furnished by RHCs and FQHCs.

### *Audio-only services*

The CAA, 2022, also requires temporary coverage of audio-only telehealth services included on the Medicare Telehealth Services List as of March 15, 2022. CMS reiterates that only those telehealth services that are designated as eligible to be furnished via audio-only

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[7] *See* SSA 1834(m)(4)(C)(i) which provide geographic site requirements such as the area being designated as a rural health professional shortage area, in a county that is not included in a Metropolitan Statistical Area or from an entity that participates in certain Federal telemedicine demonstration programs.

[8] *See* SSA 1834(m)(4)(C)(ii) describing certain sites for telehealth services, including the office of a physician or a practitioner, critical access hospital (CAH), rural health clinic, Federally qualified health center, hospital, hospital-based or CAH-based renal dialysis center, skilled nursing facility, community mental health center, and certain renal dialysis facilities.

technology as of March 15, 2022, will continue to be covered during the 151-day period after the PHE ends. A list of services that involved audio-only interaction that are included on the Medicare Telehealth Services List during the PHE is available at the CMS website.

CMS proposes that, beginning CY 2023, a physician or other qualified health care practitioner billing for audio-only telehealth service must append CPT modifier "93" (Synchronous telemedicine service) to Medicare audio-only telehealth claims. CMS proposes that RHCs, FQHCs and opioid treatment programs (OTPs) would also use modifier "93" when billing for audio-only telehealth services.

### Use of Modifiers for Medicare Telehealth Services Following the End of the PHE

Under the PFS, there are two payment rates for many physicians' services: the facility rate and the non-facility rate (or office rate). The PFS facility rate is the amount generally paid to a professional when a service is furnished in a setting of care (e.g., hospital), where Medicare is making a separate payment to a facility entity (i.e., a facility fee) in addition to the payment to the billing physician or practitioner. The facility fee reflects the facility's costs associated with the service (such as clinical staff, supplies and equipment) and is paid in addition to what is paid to the professional under the PFS. Place of Service (POS) "02" indicates the payment rate includes a facility fee.

To make appropriate payment for telehealth services during the PHE, CMS instructed providers billing for Medicare telehealth services to report the POS code that would have been reported had the service been performed in person. To implement this change, CMS finalized the use of the CPT telehealth modifier (modifier "95"[9]) for the duration of the PHE. The modifier is to be used for services furnished via telehealth along with the POS code where the service would have occurred had it not been furnished via telehealth (e.g., POS 02).

CMS proposes that Medicare telehealth services furnished within 151 days after the end of the PHE will continue to be processed for payment as Medicare telehealth claims when accompanied with the modifier "95", along with the POS code that would have been reported had the service been furnished in-person.

On the 152nd day after the PHE, CMS clarifies that pre-pandemic rules will apply and only the appropriate POS can be included for payment as a telehealth claim. CMS further clarifies that during this period, the POS indicators for Medicare telehealth will be POS "02" (Telehealth Provided Other than in Patient's Home) and POS "10" (Telehealth Provided in Patient's Home). Payment for Medicare telehealth services during this period will be made at the PFS facility payment rate for either of the POS codes. Also, CMS proposes to align the facility rate for POS "10" and POS "02". It is important to note, that CMS expects most telehealth claims will include POS "02" with limited exceptions. For example, POS "10" would include claims for Medicare telehealth mental health services.

CMS proposes that supervising practitioners continue to include the "FR" modifier on any applicable telehealth claim when required to be present through an interactive real-time, audio and video telecommunications link.

[9] Per the American Medical Association, modifier "95" is for synchronous telemedicine service rendered via a real-time interactive audio and video telecommunications system.

## Other Non-Face-to-Face Services Involving Communications Technology under the PFS

### Expiration of the PHE Flexibilities for Direct Supervision Requirements

Under Medicare Part B, certain types of services, including diagnostic tests, services incident to physicians' or practitioners' professional services, and other services, must be furnished under specific minimum levels of supervision by a physician or practitioner. One level of supervision is direct supervision, which requires the immediate availability of the supervising physician or other practitioner.

During the PHE, CMS changed the definition of "direct supervision" for diagnostic tests, physicians' services and some hospital outpatient services to allow the supervising professional to be immediately available through virtual presence using real-time audio/video technology. CMS reiterates that after December 31 of the year in which the PHE ends, the pre-PHE rules for direct supervision would apply. CMS seeks information on whether to make permanent the flexibility to meet the immediate availability requirement for direct supervision through real-time, audio/video technology. CMS also seeks comment on potentially allowing immediate availability for direct supervision through virtual presence using real-time, audio/video technology for only a subset of services. CMS emphasizes its need for more information as it considers whether to make permanent a temporary exception to the direct supervision policy.

## Non-Face-to-Face Services/ Remote Therapeutic Monitoring Services

Remote Therapeutic Monitoring (RTM) is a family of five codes created by the American Medical Association's (AMA's) CPT Editorial Panel in October 2020, valued by the AMA's Resource-Based Relative Value Scale (RVS) Update Committee (RUC) at its January 2021 meeting, and finalized for Medicare payment in the CY 2022 PFS final rule. The RTM codes include three PE-only codes and two professional work, treatment management codes. However, in the CY 2022 PFS Final Rule regarding treatment management codes, CMS expressed concern about the inclusion of clinical labor in codes that could be billed by qualified nonphysician healthcare professionals because Medicare Part B does not include a benefit for services furnished "incident to" the services of some types of qualified nonphysician healthcare professionals, including clinical social workers (CSWs), certified registered nurse anesthetists (CRNAs), physical therapists (PTs), occupational therapists (OTs), and speech-language pathologists (SLPs).

For CY 2023, CMS proposes to develop four new codes, including two HCPCS G codes,[10] that allow certain qualified nonphysician healthcare professionals to furnish RTM services. Also, given the proposed G codes, CMS proposes to eliminate the previously finalized treatment codes.

[10] The two proposed G codes are: GRTM3 (Remote therapeutic monitoring treatment assessment services, first 20 minutes furnished personally/directly by a nonphysician qualified health care professional over a calendar month requiring at least one interactive communication with the patient/caregiver during the month); and GRTM4 (Remote therapeutic monitoring treatment assessment services, additional 20 minutes furnished personally/directly by a nonphysician qualified health care professional over a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month (List separately in addition to code for primary procedure)).

The other two G Codes[11] CMS proposes are to allow general supervision of auxiliary personnel. One G code is a base code and the other is an add-on code that includes clinical labor activities (e.g., incident to services such as communicating with the patient, resolving technology concerns, reviewing data, updating and modifying care plans, and addressing lack of patient improvement) that can be furnished by auxiliary personnel under general supervision.

Lastly, CMS provides an overview of the new RTM device code for cognitive behavioral therapy (CBT) monitoring (989X6)[12], which during the October 2021 CPT Editorial Panel meeting replaced two temporary codes (0702T and 0703T)[13] related to CBT monitoring. CMS notes that the new code is anticipatory, and so it agreed with the RUC recommendation that the code be contractor priced until more information is learned.

## Evaluation and Management (E/M) Visits

Over the past several years, CMS has engaged with the AMA and other stakeholders in a process to update coding and payment for office/outpatient (O/O) evaluation and management (E/M) visits, with recent changes taking effect January 1, 2021, for the O/O E/M code visit family. For example, AMA's CPT Editorial Panel redefined the O/O E/M visits, so that visit level would be selected based on either the amount of practitioner time spent performing the visit or the level of medical decision-making (MDM).

For prolonged O/O services, in prior rulemaking, CMS did not accept the revisions and instead created a separate code (G2212) for reporting such services. CMS also created an add-on code (G2211 – O/O E/M visit complexity) that would be reported with O/O E/M codes for care related to a patient's single, serious or complex chronic condition(s). However, the CAA, 2021, imposed a moratorium on Medicare payment for these services (G2211) until January 1, 2024.

For CY 2023, the AMA CPT Editorial Panel has revised the rest of the E/M visit code families (except critical care services) to match the general framework of the O/O E/M. For purposes of the Proposed Rule, CMS refers to these other E/M visit code families as "Other E/M" visits. In the Proposed Rule, CMS proposes policies addressing coding and revaluation of Other E/M visits beginning CY 2023 and provides additional information to clarify application of Other E/M visits. Also, CMS proposes delaying implementation of the previously finalized split (or shared) visit policy.

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[11] The two other proposed G codes are: 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 evaluation and management services); and 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 over a calendar month; each additional 20 minutes of evaluation and management services during the calendar month (List separately in additional to code for primary procedure)).

[12] Category 1 CPT code 989X6, Cognitive Behavioral Therapy Monitoring (Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, cognitive behavioral therapy, therapy adherence, therapy response); initial set-up and patient education on use of equipment; device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days).

[13] 0702T (Remote therapeutic monitoring of a standardized online digital cognitive behavioral therapy program ordered by a physician or other qualified health care professional; supply and technical support, per 30 days) and 0703T (Remote therapeutic monitoring of a standardized online digital cognitive behavioral therapy program ordered by a physician or other qualified health care professional; management services by physician or other qualified health care professional per calendar month) (e.g., respiratory system status, musculoskeletal system status, cognitive behavioral therapy, therapy adherence, therapy response).

Regarding Other E/M visits (e.g., hospital inpatient or observation care, Hospital or Observation Discharge Day Management, Emergency Department Visits), for CY 2023, CMS proposes to generally adopt the revised CPT E/M Guidelines for Other E/M visits and general CPT framework (except for prolonged services). The CPT E/M Guidelines are available online. Like the CPT E/M Guidelines for Other E/M visits, CMS proposes practitioner time or MDM may be used to select the E/M level. CMS clarifies that history and physical exam would be considered as qualifying activities, as medically appropriate, and would not be used to select visit level. Also, CMS makes clear that it is not adopting the CPT E/M guidelines where a billable unit of time is considered to have been attained when the midpoint is passed.

In the Proposed Rule, CMS indicates that Other E/M prolonged services would be reported under one of three proposed G codes (GXXX1, GXXX2, and GXXX3). CMS also notes there would be one G code for each family for which prolonged services would apply: inpatient/observation visits; nursing facility visits; and home or residence visits. Table 18 of the Proposed Rule (pg. 347) provides the proposed time thresholds to report Other E/M prolonged services.

CMS indicates that, for payment purposes, physician and NPPs are not classified as having the same specialty, and the PFS does not recognize subspecialties. However, CMS indicates it is continuing to consider whether it could better align this payment taxonomy with clinical practice (i.e., where CMS may consider NPPs as working in the same specialty as the physicians with whom they work or recognize subspecialties).

### Hospital Inpatient or Observation Care (CPT Codes 99218 – 99236)

#### Coding Changes and Visit Selection for Hospital Inpatient or Observation Care Services

CMS notes that, effective January 1, 2023, per the CPT Editorial Panel, seven observation care codes will be deleted[14] and nine codes[15] revised to create a single set of codes for inpatient and observation care which will be added. The new code family includes three initial hospital or observations care codes.[16] In addition, the CPT Editorial Panel changed the code descriptors for "same-day discharge" codes to allow level of service to be based on total time or MDM and updated the documentation requirements.

CMS proposes to adopt the revised CPT codes 99221-99223 and 99231-99236. Regarding time, CMS proposes that when a physician or practitioner selects CPT codes 99221-99223 and 99231-99236 based on time, the number of minutes specified in the descriptor for the relevant CPT code must be "met or exceeded." For 99213-99236, time counted towards the code is "per day". As such, CMS proposes to adopt the 2023 CPT Codebook instruction that "per day" (or "date of encounter"), means the "calendar date". If the service is continuous before and through midnight, all the time may be applied to the reported date of the service, that is, the calendar date the encounter began.

Lastly, CMS proposed to keep its policy that a billing practitioner shall bill only one of the hospital inpatient or observation care codes for an initial visit, a subsequent visit, or inpatient

[14] Deleted CPT codes are three initial observation care codes (99218, 99219, 99220) and three subsequent observation codes (99224, 99225, 99226).
[15] Revised CPT codes are six hospital inpatient care codes and three codes under "Observation or Inpatient Care Services (including Admission and Discharge') which are frequently referred to as "same-day discharge" codes; the "same-day discharge codes" were also renamed to "Hospital Inpatient or Observation Care (Admission and Discharge)" (99234-99236).
[16] The codes in the new code family are CPT codes Initial hospital inpatient or observation care (99221-99223), and three subsequent inpatient or observation care codes, (99231-99233).

or observation care (including admission and discharge), as appropriate, once per calendar date.

### Proposed "8 to 24 Hour Rule" for Hospital Inpatient of Observation Care

CMS proposes to retain the "8 to 24-hour rule" regarding payment of discharge CPT codes 99238 (Hospital inpatient or observation discharge day management; 30 minutes or less) and 99239 (more than 30 minutes). Specifically, CMS proposes that if a patient receives fewer than 8 hours of hospital inpatient or observation services, then the practitioner would bill only initial inpatient or observation care (described by CPT codes 99221, 99222, or 99223, as appropriate). Alternatively, if a beneficiary receives hospital inpatient or observation services for at least 8 hours but fewer than 24 hours, then the practitioner bills "same-day discharge" codes (i.e., CPT codes 99234, 99235, or 99236). If the beneficiary is admitted for hospital inpatient or observation care and is then discharged after more than 24 hours, the practitioner would bill an initial hospital inpatient or observation care code (99221-99223) for the date of admission, and a hospital discharge day management service (99238-99239) on the date of discharge.

### Proposed Definition of Initial and Subsequent Hospital Inpatient or Observation Visit

According to the 2023 CPT Codebook, CMS indicates an "initial" service may be reported when "the patient has not received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice during the stay. When advanced practice nurses and physician assistants are working with physicians they are in the exact same specialty and subspecialty as the physician." According to CMS, the revised CPT codes 99231-99233 describe the subsequent hospital inpatient or observation care services similarly. However, although the CPT Codebook makes reference to subspecialities, CMS does not recognize subspecialties. For example, as noted in the Medicare Claims Processing Manual (pub 100-04) chapter 26, section 10.8), CMS's longstanding taxonomy for PFS services, for payment purposes, is that physicians and NPPs are not classified as having the same specialty, and the PFS does not recognize subspecialties. While CMS notes it is considering whether it could better align payment taxonomy with clinical practice, it does not make any proposals related to taxonomy. However, as the agency does not recognize subspecialties the agency proposes different definitions of "initial" and "subsequent" service.

CMS proposes an "initial" service to be "one that occurs when the patient has not received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the same specialty who belongs to the same group practice during the stay." Regarding "subsequent" service, CMS proposes it would be "one that occurs when the patient has received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the same specialty who belongs to the same group practice during the stay." CMS also restates that elsewhere in the Proposed Rule, the agency proposes that for both the initial and subsequent visits, when advanced practice nurses and physician assistants are working with physicians, they are always classified in a different specialty than the physician.

### Transitions Between Setting of Care and Multiple Same-Day Visit for Hospital Patients Furnished by a Single Practitioner

CMS proposes to retain its current policy that for the purposes of reporting an initial hospital inpatient or observation care service, a transition from observation status to inpatient status does not constitute a new stay. Similarly, CMS proposes to retain the policy that if a patient is

seen in a physician's office on one date and receives care at a hospital (for inpatient or observation care) on the next date from the same physician, both visits are payable to that physician, even if less than 24 hours has elapsed between the visit and the hospital inpatient or observation care. Alternatively, if the patient is admitted to outpatient observation or as a hospital inpatient via another site of service (e.g., hospital ED, physician's office, nursing facility), then all services provided by the physician in conjunction with that admission are considered part of the initial hospital inpatient or observation care when performed on the same date as the admission. CMS notes that this policy differs somewhat from the 2023 CPT Codebook.

### Impact of Changes to Hospital Inpatient or Observation Codes on Billing and Claims Processing Policies

CMS proposes that starting in CY 2023, hospital inpatient and observation care by physicians will be billed using the same CPT codes (99221-99223, 99231-99233, and 99238-99239), but that the current observation codes (99218-99220 and 99224-99226) are being deleted. CMS seeks feedback on potential challenges to billing or claims processing policies for hospital inpatient or observation care, including possible impact on billing for patients during a global period, documentation requirements, and modifiers associated with hospital inpatient or observation care claims.

### Prolonged Services for Hospital Inpatient or Observation Care

In the Proposed Rule, CMS provides an overview of various changes the CPT Editorial Panel made to prolonged codes that previously could be billed with inpatient codes, including the creation of code 993X0 which is to report prolonged total time with and without direct patient contact on the date of an inpatient service. However, CMS does not propose to adopt CPT code 993X0 and instead proposes to create a single G code (GXXX1) that describes a prolonged service and that applies to CPT codes 99223, 99233, and 99236 (assuming the E/M visit level selected is based on time).

CMS clarifies that it proposes GXXX1 instead of CPT code 993X0 because the agency disagrees with the CPT instruction regarding the point in time at which the prolonged code should apply. CMS reiterates its belief the that the prolonged code is only applicable after both the total time described in the base E/M code descriptor is complete and the full 15 minutes described by the prolonged code are complete as well. CMS also clarifies that the prolonged service period described by GXXX1 can begin 15 minutes after the total times for CPT codes 99223, 99233 and 99236 have been met. For example, a practitioner could bill GXXX1 for base code CPT 99223 when 105 minutes is reached for an initial visit on the date of the encounter; the prolonged service would begin at minute 90 and the 15-minute increment for GXXXX1 could be billed at minute 105.

## Hospital or Observation Discharge Day Management (CPT Codes 99217, 99238, and 99239)

Effective January 1, 2023, the CPT Editorial Panel deleted the observation discharge code, CPT code 99217 (Observation care discharge day management) and revised the two hospital discharge day management codes,[17] so that these two codes may be billable for discharge of hospital inpatient or observation patients. CMS proposes to adopt the revised CPT codes 99238 and 99239.

[17] CPT codes 99238 (Hospital inpatient or observation discharge day management; 30 minutes or less) and 99239 (more than 30 minutes).

While the CPT Editorial Panel deleted CPT code 99356 (Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour) and CPT code 99357 (each additional 30 minutes) and replaced them with CPT code 993X0,[18] CMS does not adopt these changes. Instead, CMS makes clear its belief that CPT code 99239 already includes all services furnished during the surveyed timeframe, and, as a result, CMS indicates it would not be appropriate to allow any prolonged codes to be billed with CPT code 99239 as a base code.

### Emergency Department Visits (CPT Codes 99281-99285)

Given the CPT Editorial Panel revised CPT codes 99221-99223 to include both inpatient hospital and observation care services, CMS proposes to modify its policy regarding when to bill ED codes CPT codes for hospital inpatient care (CPT codes 99221 through 99223) to clarify that these policies apply to observation care billed under CPT codes 99221 through 99223.

CMS also proposes that prolonged services described by HCPCS codes GXXXX1-GXXX2 would not be reportable in conjunction with ED visit codes, because the ED visit codes are not reported based on the amount of time spent with the patient.

### Additional Visits

In the Proposed Rule, CMS also addresses nursing facility visits (CPT Codes 99304-99318), nursing facility discharge management (CPT Codes 99315-99316), annual nursing facility assessment (CPT Codes 99318), and cognitive assessment and care planning (CPT Code 99483), and consultations (CPT Codes 99241-99255).

### Split (or Shared) Visits

A split (or shared) visit refers to an E/M visit that is performed ("split" or "shared") by both a physician and a non-physician practitioner (NPP) who are in the same group. In the Proposed Rule, CMS notes that it in the CY 2022 PFS final rule, it finalized a policy for E/M visits furnished in a facility setting to allow payment to a physician for a split (or shared) visit (including prolonged visits) where a physician and NPP provide the service together (not necessarily concurrently) and the billing physician personally performs a substantive portion of the visit. CMS notes that there were stakeholder concerns regarding the agency's definition of "substantive portion" because only time (i.e., more than half of total time) would have been used for purposes of defining what is the substantive portion of the visit. The CY 2022 split (or shared) visit policy was to take effect January 1, 2023.

CMS continued to hear concerns from stakeholders regarding implementation of the split (or shared) visit policy, and requests that the agency recognize MDM as included in the substantive portion. After consideration, CMS proposes to delay implementation of the updated substantive portion definition until January 1, 2024. CMS reiterates its belief that it is appropriate to define the substantive portion of a split (or shared) service as more than half of the total time. CMS also indicates the one-year delay provides another comment opportunity and more time for CMS to consider more recent feedback and evaluate whether there is a need for additional rulemaking on this aspect of the policy.

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[18] 993X0 - Prolonged inpatient or observation evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time.

## Geographic Price Cost Indices (GPCIs)

By statute, CMS must develop separate Geographic Practice Cost Indices (GPCIs) to measure the relative cost difference among localities compared to the national average for the work, practice expense (PE) and malpractice (MP) fee schedule components. CMS is required to review and potentially adjust the GPCIs at least every 3 years. In the Proposed Rule, CMS proposes new GPCIs beginning for CY 2023. Addenda D and E of the Proposed Rule, available on the CMS website, include the proposed GPCIs and summarized Geographic Adjustment Factors (GAFs). Also, the proposed GPCI cost share weights for CY 2023 and the rebased and revised cost share weights with the proposed MEI are available in Table 19 of the Proposed Rule (pg. 362). As provided in Table 19, with the proposed MEI, the cost share weights would change once implemented. For example, the Work category would decrease to 47.261 percent from 50.866 percent, PE would increase to 51.341 percent from 44.839 percent and MP would decrease to 1.398 percent from 4.295 percent. In developing the work and MP GPCIs, the employee wage index component of the PE GPCI and the GAFs, CMS identified technical refinements to the methodology which are provided in more detail in the Proposed Rule but address the occupation groups, occupation does, occupation codes used for the Employee Wage Index and the GAF weight adjustment.

In addition, CMS seeks comment on potentially incorporating the rebased and revised MEI cost share weights into the CY 2024 GPCIs, including whether CMS should phase in this adjustment over a two-year period.

Regarding the GPCI floor generally, the Consolidated Appropriations Act of 2021 extended the 1.0 floor for the work GPCI until December 31, 2023. Therefore, in the Proposed Rule, CMS makes clear the 1.0 floor on the work GPCI is will continue through CY 2023.

## Proposal to Allow Audiologist to Furnish Certain Diagnostic Tests Without a Physician Order

CMS provides an overview of various stakeholder comments and requests regarding removal of the treating physician or practitioner order requirement for diagnostic audiology hearing and balance assessment services. In response, CMS proposes to remove the order requirement under certain circumstances for certain audiology services furnished personally by an audiologist for non-acute hearing conditions. Table 29 (pg. 429) of the Proposed Rule provides a list of services and codes for test that an audiologist may provide without a physician or NPP order or referral. In addition, CMS proposes a HCPCS code (GAUDX) that would be used by the audiologist to bill for audiology services once every 12 months for a beneficiary. To avoid potential duplicate billing (e.g., two audiologists billing in a 12-month period), CMS indicates it plans to establish system edits.

## Rebasing and Revising the Medicare Economic Index

The Medicare Economic Index (MEI) reflects the weighted-average annual price change for various inputs involved in furnishing physicians' services. The MEI is a fixed-weight input price index comprised of two broad categories: (1) physicians' own time (compensation); and (2) physicians' practice expense (PE). Additionally, it includes an adjustment for the change in economy-wide, total factor productivity (TFP) (which recently replaced the term multifactor productivity). While the MEI annual percentage change increase is not directly used to update the PFS CF, the MEI cost weights have historically been used to update the GPCI (e.g., weighting the four components of the practice expense GPCI (employee compensation, the office rent, purchased services, and medical equipment, supplies, and other miscellaneous

expenses) and to recalibrate the relativity adjustment to ensure that the total pool of aggregate PE RVUs remains stable relative to the pool of work and MP RVUs. CMS proposes to rebase and revise the MEI using a methodology that uses publicly available data sources for input costs that represent all types of physician practice ownership (not only self-employed).

In the Proposed Rule, CMS details several proposals regarding derivation of cost categories and associated cost share weights and selection of the price proxies in the MEI. Table 30 of the Proposed Rule (pg. 464) provides proposed 2017-based MEI and 2006-based MEI cost categories and weights. In addition, table 2 provides the percent distribution of major physician expense components in 2006 and 2017, as a result of the proposed updates to the MEI cost weights. The proposed 2017-based MEI annual percent changes differ from the 2006-MEI annual percent changes by 0.1 to 0.2 percent points of any given year since 2016.

| | Weight | |
|---|---|---|
| **RVU Component** | **Current** | **Proposed** |
| | **2006** | **2017** |
| Physician Work | 50.9% | 47.3% |
| Practice Expense | 44.8% | 51.3% |
| Malpractice or Professional Liability Insurance | 4.3% | 1.4% |
| Total | 100.0% | 100.0% |

**Table 2. Percent Distribution of Major Physician Expense Components: 2006 and 2017**

It is important to note that CMS anticipates that full implementation of the MEI could have significant impacts if done over a single year. As such, CMS does not propose fulling implementing the rebased and revised MEI for CY 2023. CMS seeks comment on implementation, including potential four-year transition. Additional insights, by specialty, regarding the potential impact of a rebased and revised MEI are available in the Proposed Rule (pg. 1515).

## Requiring Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

Many drugs, including biologics, are payable under Medicare Part B (usually at average sales price plus 6 percent) and are dosed in a variable manner such that the entire amount identified on the vial or package is not always administered to the patient. The FDA-approved labeling for a drug packaged in a single-dose container typically states that any extra amount of the drug remaining after the dose is administered must be discarded. When discarded after administering a dose to a Medicare beneficiary, payment is provided for the unused and 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 (Drug amount discarded/not administered to any patient) is a Healthcare Common Procedure Coding System (HCPCS) Level II modifier used to report the amount of a drug that is discarded and eligible for payment. Medicare Part B data for discarded amounts of drug (based on the JW modifier) have been published on the CMS website annually for calendar years beginning in 2017.

The Infrastructure Investment and Jobs Act, which was signed into law on November 15, 2021, requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges for the drug in a given calendar quarter. A refundable single-

dose container or single use package drug does not include a radiopharmaceutical or imaging agent, certain drugs requiring filtration, and certain new drugs.

In the Proposed Rule, CMS proposes and provides detail regarding how discarded amounts of drugs are determined; a definition of which drugs are subject to refunds (and exclusions); when and how often CMS will notify manufacturers of refunds; when and how often payment of refunds from manufacturers to CMS is required; refund calculation methodology (including applicable percentages); a dispute resolution process; and enforcement provisions.

Regarding discarded amounts, on the claim form, the amount of drug administered is billed on one line (reflected as billing units in the unit field); discarded amounts are billed on a separate line with the JW modifier (reflected as billing units in the unit field). The term “billing unit” is defined in law as the identifiable quantity associated with a billing and payment code, as established by the Secretary. CMS proposes to use the JW modifier or any successor modifier that includes the same data to determine the total number of billing units of a billing and payment code to calculate the refund amount.

For consistency, CMS proposes that HOPDs and ASCs would also need to report using the JW modifier in certain circumstances. CMS proposes that the JW modifier would not be required to identify discarded amounts of drugs that are not separately payable (e.g., packaged drugs under the OPPS or ASC payment system). Similarly, CMS proposes to exclude from the refund amount those units of drugs for which payment is packaged into payment for a comprehensive ambulatory payment classification (CAPC) service under the OPPS.

In addition, CMS proposes that the JW modifier be required on claims for all single-dose container or single use drugs for which any amount is discarded (as reflected in our current policy and proposed above), and a separate modifier (“JZ”) be required on claims for these drugs when there are no discarded amounts. As proposed, all claims for single use vials or single use packages payable under Part B, either the JW modifier would be used (on a separate line) to identify any discarded amounts or the JZ modifier (on the claim line with the administered amount) would be present to attest that there were no discarded amounts. CMS welcomes comments on these proposals.

CMS proposes that for a drug to meet the definition of “refundable single-dose container or single-use package drug,” all NDCs 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.

Under law, CMS is to provide each manufacturer of a refundable single-dose container or single-use package drug with a report, for each calendar quarter on or after January 1, 2023, that includes the total number of units of the billing and payment code of such drug, if any that were discarded during a quarter and the refund amount that the manufacturer is liable. CMS proposes to send the first report to manufacturers no later than October 1, 2023. CMS proposes that refunds be paid in 12-month intervals, and also proposes establishing a dispute resolution process for manufacturers.

Regarding enforcement, CMS proposes contractors would periodically review Part B medication claims to ensure the JW modifier, JZ modifier (if adopted), and discarded drug amounts are billed appropriately and consistent with the agency’s normal claims audit policies and protocols. Also, for non-compliant manufacturers, civil monetary penalties may be imposed.

## Clinical Laboratory Fee Schedule (CLFS)

### Revised Data Reporting Period and Phase-in of Payment Reductions, and Proposals for Specimen Collection Fees and Travel Allowance for Clinical Diagnostic Laboratory Tests (CDLTs)

The Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. Under CLFS regulations, "reporting entities" must report to CMS during a "data reporting period" "applicable information" collected during a "data collection period" for their component "applicable laboratories." The Protecting Medicare and American Farmers from Sequester Cuts Act, enacted on December 10, 2021, amended certain data reporting requirements and delayed the next data reporting period. To implement the law, among other changes, CMS proposes that applicable information for CY 2024 – CY 2026 CLFS payment rates would be from the data reporting period of January 1, 2023 – March 31, 2023, and the data collection period would be January 1, 2019 – June 30, 2019.

### CLFS Specimen Collection

Generally, there is a nominal fee provided for specimen collection for laboratory testing and a fee to cover transportation and personnel expenses for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital), in addition to the amounts provided under the Medicare CLFS. In the CY 2022 PFS proposed rule, CMS requested comments on policies for specimen collection fees, how specimen collection practices may have changed during the COVID-19 PHE, and what additional resources may be needed for specimen collection of COVID-19 CDLTs and other tests after the PHE ends. However, no subsequent policies were provided in the CY 2022 PFS final rule.

Among other proposals, CMS proposes to continue paying $3 for all specimens collected in one encounter as the nominal specimen collection fee. Also, CMS proposes to include in regulation that one specimen collection fee is allowed for each single patient encounter, even if multiple specimens are drawn from one patient. CMS notes that it believes this policy is consistent with current requirements, but not clarified in regulation.

In addition, CMS proposes to clarify several policies related to the travel allowance policy, including the methodology for the CLFS travel allowance amount and when such amounts (i.e., flat-rate or per-mile travel allowance) would apply. CMS seeks comment, including alternative consideration and suggestions based on private-payor or other approaches for providing payment for travel and specimen collection.

## Removal of Selected National Coverage Determinations

CMS periodically proposes to remove NCDs that no longer reflect current medical practice, or that involve items and services that are used infrequently by beneficiaries. In the Proposed Rule, CMS proposes removing NCD 160.22, Ambulatory EEG Monitoring, for a variety of reasons, including CMS's belief that it is inconsistent with and contrary to current standards of care. CMS seeks comment on this proposed removal, including whether the NCD should be revised, rather than eliminated.

## Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act established a new Medicare Part B benefit category for opioid use disorder (OUD) treatment services furnished by opioid treatment

programs (OTPs) during an episode of care beginning on or after January 1, 2020. In the CY 2020 PFS final rule, CMS finalized policies related to coverage, enrollment and a bundled payment for treatment of OUD furnished by OTPs. Since the CY 2020 PFS final rule, CMS has made additional changes to the OTP policies to support access to care.

For CY 2023, CMS proposes several modifications to current policies governing Medicare coverage and payment for OUD treatment services furnished by OTPs including a revised methodology for pricing the drug component of the methadone weekly bundle and the add-on code for take-home supplies of methadone. Under this proposal, CMS would base the payment amount for the drug component of HCPCS codes G2067 and G2078 for CY 2023 and subsequent years on the payment amount for methadone in CY 2021 and will update this amount annually to account for inflation using the Producer Price Index for Pharmaceuticals for Human Use (Prescription). In the Proposed Rule, CMS further detailed data sources it proposes to use to inform pricing decisions and clarifies it would no longer use the TRICARE rate as an alternative pricing methodology.

In addition, CMS proposes changes to the rate for individual therapy in the bundled rate so that 45 minutes of psychotherapy is reflected in the bundle instead of 30 minutes

Also, CMS proposes to clarify that for purposes of the geographic adjustment, OUD treatment services furnished via an OTP mobile unit will be treated as if the services were furnished at the physical location of the OTP registered with DEA and certified by SAMHSA.

Lastly, CMS proposes that services to initiate treatment with buprenorphine may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. For these services, in cases where two-way audio-video communications technology is not available to the beneficiary, CMS proposes to instead allow audio-only telephone calls. CMS seeks comment on whether to allow periodic assessments to continue to be furnished using audio-only communication technology following the end of the PHE for COVID-19 for patients who are receiving treatment via buprenorphine, and if this flexibility should also continue to apply to patients receiving methadone or naltrexone.

## Medicare Part B Payment for Preventive Vaccine Administration Services

Medicare Part B covers both the vaccine and its administration for specified preventive vaccines –influenza, pneumococcal, and hepatitis B virus (HBV). In addition, there is no applicable beneficiary coinsurance and the annual Part B deductible does not apply for these vaccinations or the services to administer them. Payment for these vaccines is based on 95 percent of the Average Wholesale Price (AWP) for a particular vaccine product, except when furnished in settings for which payment is based on reasonable cost, such as a hospital outpatient department.

For CY 2022, CMS decoupled payment for certain vaccine administration services from the PFS crosswalk and finalized a payment rate of $30 for the administration of an influenza, pneumococcal, or HBV vaccine and a payment rate of $40 for the administration of COVID-19 vaccines. However, in the CY 2022 PFS final rule, CMS did not address a geographic adjustment policy for these payment rates and instead, just indicated that payments would be geographically adjusted. When CMS posted the CY 2022 payment rates for preventive vaccine administration to the seasonal influenza webpage, CMS posted locality-specific payment rates based on application of the PFS GPCIs to the finalized payment rate.

In the Proposed Rule, CMS proposes a geographic adjustment policy that would apply to preventive vaccine administration services for CY 2023 and subsequent years. CMS proposes to use the Geographic Adjustment Factor (GAF)[19] to adjust the payment to reflect the costs of administering preventive vaccines in each of the PFS fee schedule areas. Under this proposal, beginning January 1, 2023, CMS would apply the GAF to the $40 payment amount for COVID-19 vaccine administration services, so long as the emergency use authorization declaration is still in place. CMS welcomes comment on this proposal and any other factors that could be used to make this payment adjustment to reflect geographic cost differences.

In addition, CMS proposes an annual adjustment (based upon the annual increase to the MEI) to the payment amount for administration of preventive vaccines to reflect changes in cost. CMS welcomes comments on potential approaches to updating payment rates for administration of preventive vaccines other than the MEI.

During the PHE, CMS has provided additional payment for at-home COVID-19 vaccinations. CMS notes that continuing payment for at-home COVID-19 vaccination would provide CMS additional time to track utilization and trends associated with its use to inform the policy for CY 2024. CMS makes clear, at this time, it is not extending the policy to include other preventive vaccines. Therefore, for CY 2023, CMS proposes to continue the additional payment of $35.50 when a COVID-19 vaccine is administered in a beneficiary's home under certain circumstances. CMS also proposes to adjust this payment amount for geographic cost difference as done for the preventive vaccine administration services beginning CY 2023.

### Clarification on Policies for COVID-19 Vaccine and Monoclonal Antibody Products

Table 71 of the Proposed Rule (pg. 1012) provides the CY 2023 Part B payment for preventive vaccines and COVID-19 monoclonal antibodies for pre-exposure prophylaxis, including those with Emergency Use Authorization (EUA). If the EUA declaration, which is different from the COVID-19 PHE declaration, persists into CY 2023, Table 72 of the Proposed Rule (pg. 1013) demonstrates how payment for these products would change.

## Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan

In the CY 2021 PFS final rule, CMS provided a January 1, 2022, compliance date for electronic prescribing (e-prescribing) of controlled substance (EPCS) for a covered Part D drug under a prescription drug plan or an MA-PD plan. In addition to other policies related to the e-prescribing requirement, such as exemptions, CMS finalized its proposal to provide limited compliance actions from January 1, 2023 – December 31, 2023, to a non-compliance letter sent to prescribers that may be violating the EPCS requirement.

In the Proposed Rule, CMS proposes to extend the existing non-compliance action of sending letters to non-compliance prescribers for the EPCS program implementation year until December 31, 2024. In addition, CMS proposes a change to the data source used to identify the geographic location of prescribers to inform the recognized emergency exception. CMS clarifies that starting in CY 2025, the agency plans to increase the severity of penalties for non-compliant prescribers and seeks comment regarding potential penalties for non-compliant prescribers.

[19] The GAF is calculated using the three component GPCIs under the PFS (work, PE, and malpractice), and is calculated for each PFS fee schedule area as the weighted composite of all three GPCIs for each fee schedule area using the national GPCI cost share weights.

In addition, CMS proposes changes to current exceptions, such as cases where prescribers issue only a small number of Part D prescriptions in cases of recognized emergencies.

## Changes to Terminology and Payment for Skin Substitutes

CMS proposes to treat skin substitutes (including synthetic skin substitutes) as incident to supplies when furnished in a non-facility setting. CMS also proposes to include the costs of skin substitutes as resource inputs in establishing practice expense RVUs for associated physician's services effective January 1, 2024. As a result, skin substitutes would be consistently contractor priced through CY 2024. CMS also proposes to discontinue the term skin substitutes beginning January 1, 2024, and to instead refer to this suite of products as "wound care management products".

To facilitate this change, CMS proposes to assign an A code for all wound care management products for certain devices (e.g., not bandages or standard dressings, or product not otherwise eligible for separate payment).

For this transition, CMS indicates that manufacturers with an existing Q codes would need to communicate with FDA and re-apply to CMS for an A code as Q codes are discontinued. In the Proposed Rule, CMS provides additional information regarding the timing for the transition and steps manufacturers need to take to ensure continuous coverage.

## Medicare Shared Savings Program

Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare providers, may participate in the Shared Savings Program (SSP) by forming or joining an ACO. Under the SSP, providers and suppliers that participate in an ACO continue to receive traditional Medicare FFS payments, and the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements, and in some instances, may be required to share in losses if it increases health care spending.

Under the SSP, there are different participation tracks (i.e., BASIC[20] or ENHANCED[21]) that allow ACOs to assume various levels of risk. In the Proposed Rule, CMS notes concerns that, in recent years, the growth in the number of beneficiaries assigned to ACOs has plateaued, higher cost populations are increasingly underrepresented since shifting to regionally-adjusted benchmarks, and access to ACOs appears inequitable. As a result, CMS proposes numerous policies that aim to reverse these trends and advance equity within the SSP. CMS projects these changes will result in a $15.5 billion dollar decrease in spending on benefits (savings from efficiency) and $650 million in higher net shared savings payments to ACOs. Table 51 of the Proposed Rule (pg. 773) provides a summary of the proposed changes to the quality reporting requirement for performance year (PY) 2023 and subsequent PYs.

[20] The BASIC track offers a glide path for eligible ACOs to transition from a one-sided shared savings-only model to progressively higher increments of financial risk and potential reward under two-sided shared savings (otherwise referred to as performance-based risk) and shared losses models within a single 5-year agreement period.
[21] The ENHANCED track offers ACOs the opportunity to accept greater financial risk for their assigned beneficiaries in exchange for potentially higher financial rewards.

### Increasing Participation in Accountable Care Models in Underserved Communities by Providing an Option for Advance Investment Payments to Certain ACOs

In the Proposed Rule, CMS indicates it is interested in increasing participation in the SSP by easing up-front costs for inexperienced, low revenue ACOs and supporting those ACOs in providing accountable care for underserved beneficiaries. As a result, CMS proposes to make advance shared savings payments, that would be known as advance investment payments (AIPs), to certain ACOs participating in the SSP. CMS envisions this new payment option would distribute AIPs to ACOs for 2 years (to be spent over the 5 year agreement period) and payments would be recouped from any shared savings the ACO earned.

CMS proposes the following eligibility criteria for ACOs to receive AIPs: (1) Not a renewing ACO or re-entering ACO; (2) Has applied to participate in the SSP under any level of the BASIC track glide path and is eligible to participate in the SSP; (3) Is inexperienced with performance-based risk Medicare ACO initiatives; and (4) Is a low revenue ACO.[22] CMS indicates more information would be shared through subregulatory guidance and that the initial cycle to apply for AIPs would be for a January 1, 2024 start date.

While CMS anticipates ACOs will use funds in different ways, the agency offers three categorical examples of permitted use: increased staffing, social determinants of health (SDOH) strategies and health care provider infrastructure. CMS would prohibit use of AIPs for any expenditures that are not a permitted use of funds. Examples of prohibited uses include management company or parent company profit, performance bonuses, other provider salary augmentation, provision of medical services covered by Medicaid or items or activities under related to ACO quality and efficiency improvement operations. CMS seeks comment on the examples of prohibited uses and provides additional information regarding handling of funds.

For the payment amount, AIPs would be comprised a one-time payment of $250,000 and eight quarterly payments based on the number of assigned beneficiaries (max of 10,000 beneficiaries). The per beneficiary payment amount would vary for each beneficiary based on a risk factors-based score that CMS would calculate for the beneficiary. More information regarding quarterly payments is provided in Table 3. The risk factors-based score would be informed by the beneficiary's dual eligibility status and the Area Deprivation Index (ADI) national percentile ranking of the census block group of the beneficiary's primary address.[23] CMS seeks comments on the proposed schedule of the AIPs to ACOs and payment amounts, including alternative methodologies (e.g., use of HPSAs, whether a beneficiary receives a Part D low-income subsidy) to calculate an ACO's quarterly payment.

| Risk Factors - Based Score | 1-24 | 25-34 | 35-44 | 45-54 | 55-64 | 65-74 | 75-84 | 85-100 |
|---|---|---|---|---|---|---|---|---|
| Per beneficiary payment amount | $0 | $20 | $24 | $28 | $32 | $36 | $40 | $45 |

**Table 3. Proposed Quarterly Per Beneficiary Payment Amounts**

[22] Should an ACO's circumstances change during the performance year, such that they are no longer eligible to participate then CMS will cease AIP payments the following quarter that CMS made such a determination.

[23] A beneficiary who is dually eligible would receive a score of 100, whereas a beneficiary not dually eligible and residing in a census block group with an ADI in the 75th percentile would receive a risk factors-based score of 75 which corresponds to a quarterly payment of $40.

Regarding recoupment, CMS proposes to recoup AIPs from any shared savings earned by the ACO in any PY until CMS has recouped all AIPs. If the shared savings are insufficient to recoup the AIPs made to an ACO for a PY, CMS would carry forward the balance owed to the subsequent PY(s) in which the ACO achieves shared savings. If an ACO terminates its participation agreement during the participation period, the ACO must repay all AIPs it received.

CMS seeks comment on all aspects of the agency's proposals related to AIPs, including for recoupment of the AIPs made to ACOs.

**Health Equity Bonus Points for ACOs that Report All-payer eCQMs/MIPS CQMs, and are High Performing on Quality, and Serve a High Proportion of Underserved Beneficiaries**

CMS indicates that dual enrollment status is a strong predictor of poorer health care quality measure outcomes in Medicare's value-based purchasing (VBP) programs, even when accounting for other social risk factors. CMS notes that rather than risk adjusting for disparities in health status of underserved population, it would be more appropriate to adopt an approach that rewards high quality performance across all populations served by an ACO. As a result, CMS proposes to create a health equity adjustment (through the form of bonus points) designed to support those ACOs serving a high proportion of underserved individuals while also mitigating disparities in health care by encouraging all ACOs to treat underserved populations.

Specifically, CMS proposes that the health equity adjustment would be available for PY 2023 and for subsequent PYs to any ACO that reports the three eCQMs/MIPS CQMs in the Alternative Payment Model (APM) Performance Pathway (APP) measure set, that meets data completeness requirements for all three eCQMs/MIPS CQMs and administers the CAHPS for MIPS survey. CMS proposes that such ACOs may receive up to 10 additional points added to their MIPS Quality performance category score. CMS clarifies the level of adjustment would be determined based on the both the ACO's performance on quality measure and the population served by the ACOs (e.g., higher proportion of beneficiaries who are from underserved neighborhoods) or dually eligible for Medicare and Medicaid. CMS proposes to use an "underserved multiplier" for each ACO that would be determined using the higher value of either the proportion of an ACO's assigned beneficiary population that is considered underserved based on beneficiaries who are from underserved neighborhoods, identified using ADI data, or the proportion of an ACO's assigned beneficiary population that are dually eligible for Medicare and Medicaid. CMS would then multiply this underserved multiplier by a measure performance scaler to determine the ACO's health equity adjustment bonus points.

CMS also indicates it considered an alternative approach that would use a combination of these characteristics in calculating the underserved multiplier. CMS seeks comment on the alternative approach. More generally, CMS notes it is considering similar methodologies for determining underserved populations outside of the SSP and noted prior rulemaking where the agency indicates it is developing a health equity index as a potential methodological enhancement to the Part C and Part D Star Ratings that would summarize performance among groups with social risk factors access multiple measures into a single score. CMS also seeks input on incorporating assigned beneficiaries' low-income subsidy (LIS) status into the underserved multiplier.

CMS proposes to use an ACO's health equity quality performance score to determine the final sharing rate for calculating shared savings payments under the BASIC track and the ENHANCED track for an ACO that meets the proposed alternative quality performance standard allowing for application of a sliding scale based on quality performance. Also, CMS

proposes to use the ACO's health equity adjusted quality performance score to determine the shared loss rate for such ACOs.

CMS also proposes several limitations on the availability of and the amount of the health equity adjustment bonus payments. Also, in the Proposed Rule (pg. 759-762), CMS outlines the calculation steps and provides examples of the determination of health equity adjustment bonus points and the application of these bonus points to an eligible ACO's MIPS Quality performance category score.

Also, CMS provides that it plans to show the calculation of the health equity adjustment for all ACOs that report on the eCQMs/MIPS CQM measures and that such information would be provided to ACOs in their reconciliation reports package.

### Smoothing the Transition to the Performance-Based Track

Since 2012, the SSP has included both one-sided financial models (shared savings only) and two-sided financial models (shared savings and shared losses) for ACOs to select. In 2018, CMS redesigned participation options so the ACOs would transition more rapidly to two-sided models but some ACOs indicated this shift deters participation. As a result, CMS proposes to allow ACOs to join under one-sided risk and remain in two-sided risk models with lower levels of risk.

Among other changes, CMS proposes a new 5-year agreement period under a one-sided model for certain ACOs. Specifically, CMS proposes to allow an ACO that enters the BASIC track's glide path at Level A and is currently at Level A may remain in Level A for subsequent PYs of the agreement period, for agreement periods beginning on or after January 1, 2024. ACOs that would be eligible to participate must meet the following requirements: the ACO is participating in its first agreement period under the BASIC track;[24] and the ACO is inexperienced with performance-based risk Medicare ACO initiatives. CMS also makes clear that eligibility for this participation option would not consider the ACO's revenue status. Also, CMS proposes that ACOs could elect to remain in Level A for the entirety of its first agreement period be made in the form and manner and by a deadline established by CMS.

CMS also proposes a pathway to transition ACOs into two-sided risk. Specifically, an ACO that is inexperienced with performance-based risk Medicare ACO initiatives may participate in the BASIC track glide path for a maximum of 2 agreement periods (once at Level A for all 5 PYs and a second time in progression on the glide path). CMS also proposes policy for the second and third agreement periods that aim to prevent ACOs from terminating their participation agreement before transitioning to two-sided risk in order to stay under the one-sided model.

In the Proposed Rule (pg. 699), Table 45 summarizes the participation option policies CMS proposes. Also, Table 46 of the Proposed Rule (pg. 700) summarizes an alternative participation option policy.

In addition, CMS proposes to update the definitions of inexperienced with performance-based risk Medicare ACO initiatives and experienced with performance-based risk Medicare ACO initiatives to allow for a rolling lookback period of the 5 most recent PYs beginning from the

[24] In the Proposed Rule, CMS further specifies that the ACO must also not be 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. Also, CMS proposes that this participation option would be available to re-entering former Track 1 ACOs.

current PY being monitored. CMS will monitor ACOs' experience level, which may impact the level of the BASIC track to which they advance in future years.

CMS seeks comment on the proposed policies regarding ACO participation options in the SSP. Specifically, CMS seeks comment on whether to extend the proposed option for certain ACOs inexperienced with performance-based risk Medicare ACO initiatives to spend an entire five-year agreement period under the one-sided model of the BASIC track for an additional agreement period for low revenue ACOs that enter the BASIC track as a new legal entity. CMS notes it is considering extending this participation option only to low revenue ACOs that enter the BASIC track as a new legal entity because other ACOs have already had time under one-sided risk and therefore do not need a second agreement period in one-sided only. Also, CMS outlines a potential alternative approach where CMS would permit low revenue ACOs to remain in a one-sided model of the BASIC Track for a second agreement period before entering the BASIC Track glide path in their third agreement.

### Determining Beneficiary Assignment Under the Shared Savings Program

Under current law, in PYs beginning on or after January 1, 2019, beneficiaries have been assigned to an ACO based, in large part, on their utilization of primary care services provided by a physician who is an ACO professional. CMS defines and establishes the list of "primary care services" by regulation.

In the Proposed Rule, CMS proposes to revise the definition of primary care services used for assignment in the SSP regulations to include the following additions: (1) Prolonged services HCPCS codes GXXX2 and GXXX3, if finalized; and (2) Chronic Pain Management HCPCS codes GYYY1 and GYYY2, if finalized. CMS seeks comment on these proposed changes and whether it should consider adding any other existing HCPCS or CPT codes or new HCPCS or CPT codes proposed elsewhere in this proposed rule to the definition of primary care services for purposes of assignment in future rulemaking.

### Extension of eCQM/MIPS CQM Incentive

In the Proposed Rule, CMS proposes to extend the incentive for reporting eCQMs/MIPS CQMs through PY 2024 to align with the timeline for sunsetting the CMS Web Interface reporting option before full reporting of the measures are required in PY 2025.

## Quality Performance Standard and Reporting

### Revising the Shared Savings Program Quality Performance Standard

In the Proposed Rule, CMS outlines its concerns that the current structure of the quality performance standard creates a cliff "all-or-nothing" scoring where an ACO may be ineligible to share in savings due to a minor difference between its MIPS Quality performance category score and the quality performance standard required to share in savings at the maximum share rate for the applicable PY. As a result, CMS proposes several changes to the SSP Quality Performance Standard.

Notably, CMS proposes to reinstate a modified sliding scale approach for determining shared savings for all ACOs regardless of how they report quality data. Beginning with PY 2023, CMS proposes specific criteria to be eligible to share in savings (e.g., scaling of shared savings rates for ACOs that fall below the 30$^{th}$/40$^{th}$ percentile quality standard but where minimum quality reporting and performance requirements are met).

### Proposal to Modify Methodology for Determining Scaled Shared Losses for the ENHANCED Track Based on Quality Performance

CMS also proposes a modification to the methodology used to determine shared losses for ACOs in the ENHANCED track. Currently, an ACO in the ENHANCED track must meet the quality performance standard to have its shared losses scaled based on its quality performance and avoid automatically facing the maximum shared loss rate of 75 percent. CMS proposes that for PY 2023, and subsequent PYs, CMS would determine the ACO's shared loss rate using a sliding scale approach for an ACO that has losses that exceed its minimum loss rate and either meets the existing quality performance standard applicable for the PY or that does not meet that standard but achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set. CMS clarifies that the ACO's quality performance score used in this calculation would reflect the ACO's MIPS Quality performance category score plus any health equity adjustment bonus points the ACO is eligible to receive, which is based on a newly proposed policy.

More generally, CMS clarifies that it proposes to apply the sliding scale approach to determine shared savings for all qualifying ACOs and will determine shared savings losses for ENHANCED track ACOs regardless of how they report quality data to CMS to maintain consistency regarding quality performance across all ACOs.

## Quality Measures

In the Proposed Rule, CMS provides Table 52 (pg. 776), which lists the measures included in the final APP measure set for SSP ACOs for PY 2022 and subsequent PYs. As related to the Proposed Rule, the information relates to CMS's proposal to establish an alternative quality performance standard for the maximum sharing rate, but that achieves a single quality performance score (10$^{th}$ percentile on 1 of the 4 outcome measures in the APP measure set). Should such a score be achieved, the ACO may be eligible to share in savings on a sliding scale. The Proposed APP measure set for eCQMs/MIPS CQM reporting for PY 2023 is available in Table 53 of the Proposed Rule (pg. 777).

### Proposed Benchmarking Policies for CMS Web Interface Measures for Performance Years 2022, 2023, and 2024

As noted above, Table 52 of the Proposed Rule (pg. 776) includes the outcome measures in the APP measure set and the collection type of those measures, including the CMS Web Interface. ACOs will have the option to report via the Web Interface for the 2022, 2023, and 2024 PYs only. In the CY 2021 PFS Final Rule, CMS provided that, under the APP, the quality performance score for an ACO will be calculated using the same benchmarks that are established under MIPS. Measure benchmarks established under MIPS are based on performance by collection type (e.g., eCQM, MIPS CQM) using data from all available sources. In addition, CMS uses the benchmarks from the corresponding year of the SSP to score the CMS Web Interface measure for purposes of the MIPS Quality performance category.

However, when CMS extended the CMS Web Interface as a collection type, the agency did not address policies to establish the performance benchmark and minimum attainment level for PYs 2022-2024. Generally, CMS proposes to apply previously established benchmark policies for the CMS Web Interface measures under the SSP for PYs 2022-2024.

### Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health Measures and Future Measure Development - RFI

CMS notes that health equity and addressing health disparities continue to be high priorities for the agency through the inclusion of health equity initiatives in CMS programs. In the Proposed Rule, CMS seeks comment on the potential future inclusion of two new structural measures in the APP measure set: Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health.[25] CMS notes that if a measure is adopted in the traditional MIPS program, the agency will consider proposing, in future rulemaking, the addition of this measure as an eCQM/MIPS CQM under the APP beginning in PY 2025.

CMS seeks comment on the measures for potential adoption. CMS notes it may consider including additional quality measures in the future that would assess how well ACOs address the social needs of Medicare beneficiaries more directly. However, CMS seeks input specifically on "Screen Positive Rate for Social Drivers of Health", regarding the value of implementing a quality measure that indicates a patient's social needs as a part of the quality of care provided to them.

CMS also provides a series of questions regarding health equity and the SSP, including:

- How to best implement the measures and how they could further drive health equity and health outcomes under the SSP?
- What are the possible barriers to implementation of the measures in the SSP?
- What impact would the implementation of these measures in the SSP have on the quality of care provided for underserved populations?
- What type of flexibility with respect to the social screening tools should be considered should the measures be implemented? While supporting flexibility, how can we advance the use of standardized, coded health data within screening tools?
- Should the measures, if implemented in the future, be considered pay-for-reporting measures?

## Financial Methodology

In the Proposed Rule, CMS proposes a combination of modifications to the SSP's benchmarking methodology and financial models to encourage sustained participation by ACOs in the program and remove barriers serving medically complex and low-income populations.

Regarding the benchmarking methodology, CMS proposes to incorporate a prospective, external factor for updating the benchmark; adjusting rebased benchmarks to account for an ACO's prior savings; and reducing the impact of regional adjustments on ACO benchmarks. For example, CMS proposes to incorporate a prospectively projected administrative growth factor into a three-way blend with national and regional growth rates to update an ACO's historical benchmark for each PY in the ACO's agreement period. Also, among several other changes, CMS proposes to reduce the current 5 percent cap on negative regional adjustment to 1.5 percent and to gradually decrease the negative regional adjustment amount as an ACO's proportion of dual eligible Medicare and Medicaid beneficiaries increases or its weighted-average prospective hierarchical condition category (HCC) risk score increases.

[25] The measure Screening for Social Drivers of Health assesses the percentage at which providers screen their adult patients for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety. Alternatively, the measure Screening for Social Drivers of Health assesses the rate at which providers screen beneficiaries 18 years and older for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety.

CMS indicates it is considering a longer-term approach for use of administratively set benchmarks that are decoupled from ongoing observed fee-for-service spending.

Also, CMS proposes changes regarding how it conducts annual risk adjustments to better account for medically complex, high-cost populations and to guard against coding intensity initiatives to increase risk scores, and also proposes a methodology to increase opportunities for low revenue ACOs participating in the BASIC track to share in savings. CMS proposes such changes for the risk adjustment methodology for the agreement periods beginning on or after January 1, 2024.

CMS also proposes a policy to increase opportunities for low revenue ACOs to share in savings. by expanding the eligibility criteria to qualify for shared savings such that certain low revenue ACOs participating in the BASIC track may share in savings even if the ACO does not meet the minimum savings rate (MSR), as required under law.

### COVID-19 Public Health Emergency

CMS notes that agreement periods starting in 2022 are the first agreement periods for which 2020 and 2021 serve as benchmark years for ACOs in the SSP. Also, some stakeholders have expressed concern that the policy adjustments made in response to the PHE for COVID-19 may not fully address the potential for relatively lower expenditures resulting from lower utilization by non-COVID-19 patients. CMS notes that several factors, including the proposal to utilize a three-way blend of the Accountable Care Prospective Trend[26] national-regional growth rates would help mitigate potential adverse effects of the PHE for COVID-19 on historical benchmarks, while also protecting against unanticipated variation in PY expenditures and utilization resulting from a future PHE. CMS seeks comment on this analysis and insights regarding the impact of the PHE on SSP ACOs' expenditures.

### Reducing Undue Administrative Burden and Other Policy Refinements

CMS indicates its aim to reduce administrative burdens on ACOs. CMS proposes updated policies and refinement for January 1, 2023, implementation. For example, CMS proposes to eliminate the requirement that ACOs submit marketing materials to CMS for approval prior to disseminating notifications to beneficiaries and participants, reducing the frequency of certain beneficiary notifications, streamlining the SNF 3-Day Rule Waiver application review process and recognizing ACOs structured as OHCAs for data sharing purposes.

### Seeking Comment on Incorporating an Administrative Benchmarking Approach into the Shared Savings Program

CMS provides an overview of various policies in the Proposed Rule, such as incorporating a prior saving adjustment, mitigating the impact of the negative regional adjustment, and modifying the benchmark update to incorporate a prospective, external factor (Accountable Care Prospective Trend (ACPT)) that aims to address certain SSP circumstances, referred ratchet effects,[27] and features within the existing benchmarking methodology that result in selective participation. CMS seeks comment on broader changes to the benchmarking

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[26] In the Proposed Rule, CMS refers to the Accountable Care Prospective Trend (ACPT) which is a projective administrative growth factor and variant of the United States Per Capita Cost (USPCC).

[27] In the Proposed Rule, CMS identifies two concerning ways in which ACO spending reductions can lead lower benchmarks, and refers to these two ways as "ratchet" effects. The ratchet effects are: (1) downward pressure on an individual ACO's benchmark resulting from the impact of its achieved spending reductions on its historical benchmark expenditures, regional adjustment, and update factor; and (2) downward pressure on benchmarks due to program-wide spending reductions across all ACOs. CMS provides that as more Medicare FFS beneficiaries are assigned to ACOs, this program level ratcheting effect diminishes incentives to participate in the SSP.

methodology that may be needed to further strengthen incentives for providers and suppliers to participate in the SSP and generate savings while preserving a mechanism for convergence to a consistent regional benchmarking approach.

Among other changes, CMS describes an administratively-established benchmarking approach. Under this approach, benchmarks would be allowed to rise above realized FFS expenditure growth as ACOs generate savings, allowing ACOs to retain more of their savings and thus strengthening incentives to participate and achieve savings. Over time, use of this administratively set growth rate would allow for a wedge to accrue between average benchmarks and realized spending reductions, offering greater and more sustainable savings opportunities over the long-term for both Medicare and ACOs. More importantly, average benchmark growth would only exceed realized FFS spending growth to the extent that ACOs reduce spending, such that benchmarks remain at or below FFS spending levels projected in the absence of ACO participation. Figure 3 of the Proposed Rule (pg. 963) provides an illustrative depiction of administratively-established benchmarking. CMS invites comments on the concept and design of an administratively established benchmarking methodology.

## Updates to the Quality Payment Program

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Quality Payment Program (QPP) for eligible clinicians. Under the QPP, Merit-based Incentive Payment System (MIPS) eligible clinicians can participate via one of two tracks – the MIPS (reporting available via traditional MIPS or MIPS Value Pathways (MVPs)) or the Advanced Alternative Payment Models (Advanced APMs). Eligible clinicians participating in MIPS are subject to a MIPS payment adjustment based on their relative performance in four performance categories: Cost, Quality, Improvement Activities (IA) and Promoting Interoperability (PI). Alternatively, if an eligible clinician participates in an Advanced APM pathway and achieves Qualifying APM Participant (QP) status, they are excluded from the MIPS reporting requirements and payment adjustment. QPs for the year are eligible to receive a 5 percent lump sum incentive payment until CY 2024, or a differential payment update under the PFS for payment years beginning in 2026. In the Proposed Rule, CMS aims to increase opportunities for Advanced APM participation and advances policies regarding clinical participation through MVPs, among other changes.

Generally, the Proposed Rule sets forth changes to the QPP starting January 1, 2023, except as otherwise noted for specific provisions. The Proposed Rule provides additional detail regarding CMS's measurement efforts, makes refinements to how clinician would be able to participation in the MVPs and encourages participation in Advanced APMs. CMS also provides a Fact Sheet on the Quality Payment Program website and other resources.

### MIPS Value Pathways (MVPs)

In the CY 2020 PFS final rule, CMS establishes MVPs, which are a subset of measures and activities that are relevant to a specialty, medical condition or specific patient population, and can be used to meet MIPS reporting requirements. CMS notes that it intends for MVPs to help practices prepare to take on and manage financial risk, for example, through Advanced APMs. In the CY 2022 PFS final rule, CMS finalized policies regarding MVP reporting by subgroup and reporting policies, among several other policies. MVPs will be available for voluntary reporting beginning with the CY 2023 MIPS performance period. CMS intends for MVPs to become the only method to participate in MIPS in future years as CMS sunsets traditional MIPS. In the Proposed Rule, CMS is also considering how best to advance health equity via the QPP, including MVPs.

### MVPs and APM Participant Reporting - RFI

In the CY 2022 PFS proposed rule, CMS requested information regarding how best to align MVPs and APMs. Some commenters noted challenges for specialties in reporting quality performance data under MIPS and their respective APM separately, resulting in additional reporting burden, among other challenges. CMS is interested in additional feedback regarding specialists' reporting of quality performance data and ways to use MVPs to obtain more meaningful performance data from primary care and specialty clinicians. Also, CMS seeks feedback on opportunities to align clinician experience with MVPs and APMs and develop scoring policies for APM participants in multispecialty groups who choose to participate in MVPs and report specialty care performance data.

### MVP Development and Maintenance Process

In the Proposed Rule, CMS notes that it aims to improve its current process for stakeholder input regarding MVP development. CMS proposes to modify the MVP development process by having the agency evaluate a submitted candidate MVP and if the MVP is "ready" for feedback, a draft version of the submitted candidate MVP would be posted on the Quality Payment Program website (https://qpp.cms.gov/). CMS would provide a 30-day feedback period before potentially including the MVP in a proposed rule. CMS requests comments on this proposal.

Similarly, CMS proposes to modify its maintenance process to promote stakeholder input. CMS proposes to allow stakeholders to submit revisions on a rolling basis throughout the year. Should submissions be potentially feasible and appropriate, CMS would host a public facing webinar and potentially adopt revisions through notice and comment rulemaking. CMS requests comments on this proposal.

### Proposed New MVPs

CMS proposes five new MVPs: advancing cancer care; optimal care for kidney health; optimal care for neurological conditions; supportive care for cognitive-based neurological conditions; and promoting wellness. Additional information regarding each newly proposed MVP and proposed revisions to the seven previously finalized MVPs is available in the Proposed Rule (Appendix 3: MVP Inventory (pgs. 2034-2066)).

### MVP Reporting Requirements and Scoring

In prior rulemaking, CMS finalized that MVPs must include the full set of PI performance category measures and CMS clarified that reporting requirements for PI measures in the MVPs will be aligned with what is established under traditional MIPS. In the Proposed Rule, CMS confirms that policies finalized for the PI performance category under traditional MIPS also apply to MVPs.

Similarly, CMS indicates that it intends to adopt scoring policies from traditional MIPS for MVP participants unless there is a compelling reason to adopt a different policy to further the goals of the MVP framework.

### Subgroup Reporting

In the CY 2022 PFS final rule, the agency finalized the subgroup[28] reporting option for clinicians choosing to report MVPs or the APP and various other details such as the

[28] In the CY 2022 PFS final rule, CMS defined a subgroup as a subset of a group which contains at least one MIPS eligible clinician and is identified by a combination of the group TIN, the subgroup identifier, and each eligible clinician's NPI.

implementation timeline; registration requirements, reporting requirements, and scoring; definitions of subgroup and other terms; eligibility requirements; application of the low-volume threshold and special status designations for subgroups; and subgroup inclusions and exclusions. In the Proposed Rule, since subgroup reporting is a new option, CMS proposes new and updated policies regarding subgroups.

CMS previously finalized definitions of an MVP Participant, single specialty group and multispecialty group. The definition of MVP Participant would only allow multispecialty groups to participate as a group for MVP reporting beginning with the CY 2023 performance period/CY 2025 MIPS payment year through the CY 2025 performance period/2027 MIPS payment year. Beginning with the CY 2026 performance period/CY 2028 MIPS payment year, only single specialty groups would be able to participate as a group for MVP reporting, and multispecialty groups will be required to form subgroups for reporting an MVP. To determine specialty, CMS had previously considered using PECOS data, but received stakeholder concerns regarding the identification of a practitioner's specialty type. As a result, CMS proposes to modify the definition of a single specialty group to clarify that it means a group that consists of one special type determined by CMS using Medicare Part B claims (as opposed to PECOS data). CMS proposes similar changes to the definition of multispecialty group to rely on Medicare Part B claims to determine specialty types. CMS seeks comment on these proposals and requests additional data sources that CMS could use to determine a group's specialty type or types.

In addition, CMS received stakeholder concerns regarding definitions finalized in the CY 2022 PFS final rule for Single Specialty Group and Multispecialty Group. Stakeholders were concerned that the definition of single specialty subgroup posed challenges for PAs and NPs, who are designated by their education credentials only, as opposed to a clinical specialty relevant to the scope of care provided. In response, CMS proposes to modify the definition of Single Specialty Group and Multispecialty Group such that specialty type would be determined by CMS using Medicare Part B claims.

Although the subgroup reporting option is new, CMS anticipates it will need to establish requirements and/or restrictions on the composition of subgroups but does not propose such policies for the CY 2023 performance period/2025 MIPS payment year. However, to inform future policies, CMS proposes that as part of the subgroup registration process, group Tax Identification Numbers (TINs) must provide a description of each subgroup that is registered. CMS indicates that, to ease burden, it would permit subgroups to select from certain common scenarios to form subgroups, when appropriate, instead of drafting a narrative description.

In addition, CMS notes that while each subgroup receives a subgroup identifier, this information is not present on any claims data. To ensure CMS can determine which subgroup a particular claim should be connected to, CMS proposes that an individual eligible clinician (represented by a TIN/National Provider Identifier (NPI) combination) may register for no more than one subgroup within a group's TIN. CMS also proposes to limit a clinician to a single subgroup per group TIN to overcome current limitations in scoring certain cost and quality measures. CMS seeks feedback regarding the frequency in which clinicians work in different capacities (e.g., different specialties) within a single group TIN and if there are ways CMS can match a clinician to a subgroup for measure reporting through Medicare Part B claims or if it can be calculated using administrative claims.

### Subgroup Scoring

In the Proposed Rule, CMS provides clarity regarding subgroup score for administrative claims measures and cost measures. While CMS generally believes subgroups can be

measured in the same way as groups, there are some exceptions as subgroups are established differently and because of variable attribution methodologies of a measure. CMS proposes to assess subgroups on measures in the cost performance category, and population health measure and outcomes-based administrative claims measure in the quality performance category, based on their affiliated group. If the subgroup's affiliated group score is not available for a measure, the measure is excluded from the subgroup's total measure achievement points and total available measure achievement points. CMS seeks comment on these proposals.

For a subgroup that registers but does not submit data as a subgroup for the applicable performance period, CMS proposes not to assign a final score for the subgroup.

### APM Performance Pathway (APP)

In the CY 2021 PFS Final Rule, CMS finalized the APP,[29] including measure sets and weights, as it effectively replaces the MIPS APM scoring standard. The APP is meant to provide a predictable and consistent reporting option and is available for reporting by any submitter type, except virtual groups. Although CMS previously finalized regulations indicating that subgroups would be scored according to the applicable MVP or APP scoring rule, no changes were made to reflect the introduction of subgroup-level reporting of the APP.

As a result, CMS understand there is ambiguity in the current rule, and proposes to disallow reporting of the APP by a subset of a group, as it was not CMS's intent to allow MIPS eligible clinicians with an APM entity to be scored at a level in between a group and the individual clinician. However, in the Proposed Rule, CMS consider potential options to permit subgroup reporting of the APP (e.g., enabling a subgroup registration option for APP reporters) but seeks comments from the public.

During the CY 2021 PFS rulemaking cycle, CMS contemplated removing the CMS Web Interface as an option for SSP ACOs to report quality. However, the agency ultimately determined to extend this option for the 2021 performance period only. In the Proposed Rule, due to stakeholder feedback and the COVID-19 PHE, CMS proposes to extend the option to report via the CMS Web Interface for PYs 2022 and 2023. Notably, for PY 2023, CMS proposes to only score Web Interface submissions for ACOs that have also submitted at least one eCQM/MIPS CQM measure from the APP measure set.

Beginning with PY 2023, CMS also proposes to allow MIPS eligible clinicians in MIPS APMs to report the APP as a subgroup. CMS generally aligns subgroup policies for MVP and APP, including eligibility and reporting.

### MIPS Performance Category Measures and Activities

#### Quality Performance Category

In the Proposed Rule, CMS proposes a variety of changes regarding the quality performance category, including amending the definition of a "high priority measure" to include quality measurement pertaining to health equity, increasing the data completeness threshold to at least 75 percent for CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years, and several modifications to the MIPS quality measure set. More information

[29] The APP is a MIPS reporting and scoring pathway for MIPS eligible clinicians who are also participants in MIPS APMs.

regarding these changes and changes to other categories is provided in Appendix 1 of the Proposed Rule (pg. 1642 – 2032).

CMS provides RFIs related to the Quality performance category. One request relates to the development of quality measures that address amputation avoidance in diabetic patients and the other is related to health equity. A list of questions regarding the health equity RFI is available in the Proposed Rule (pg. 1179-1182) and CMS notes that it seeks comment on potential approaches for measuring health equity in MIPS and MVPs: assessing the collection and use of self-reported patient characteristic and assessing patient-clinician communication.

### Cost Performance Category

CMS proposes to update the operational list of care episode and patient condition groups and codes by adding the Medicare Spending Per Beneficiary (MSPB) Clinician cost measure as a care episode group. CMS notes the MSPB Clinician cost measure takes into account the patient's clinical diagnoses at the time of an inpatient hospitalization and includes the costs of various items and services furnished during an episode of care. Also, CMS notes that there are 7 episode-based measures under development and 4 anticipated measures to begin development this year. The operational list as revised to reflect the proposal is available on the MACRA Feedback Page.

### Improvement Activities Performance Category

For the CY 2023 performance period/2025 MIPS payment year and future years, CMS proposes the following changes: adding four new improvement activities; modifying five existing improvement activities; and removing six previously adopted improvement activities. CMS notes all the proposed new improvement activities related to health equity.[30] CMS also proposes a number of modifications, including changes to the improvement activity "Practice improvements that engage community resources to support patient health goals" to better encompass social determinants of health. Appendix 2 of the Proposed Rule (pgs. 2022-2034) provides more detail regarding these proposed changes.

### PI Performance Category

In the Proposed Rule, CMS provides numerous changes and request for information regarding the Promoting Interoperability (PI) Performance Category, primarily regarding measures, such as the Query of Prescription Drug Monitoring measure and Patient Access to Health Information measure, and aspects of the PI Performance Category objectives (e.g., Health Information Exchange objective, Public Health and Clinical Data Exchange objective). Also, in the Proposed Rule, CMS reminds healthcare providers that they are not required to demonstrate that they are using updated technology to meet the CEHRT definitions immediately upon the December 31, 2022, transition date provided in rulemaking by the Office of the National Coordinator for Health Information Technology (ONC). The ONC rule requires health IT developers to make updated certified health IT available, and in CMS rulemaking the agency has required that the technology health care providers use must satisfy the definitions of CEHRT. As a result, the hospital, CAH, or MIPS eligible clinician is not required to demonstrate meaningful use of technology meeting the 2015 Edition Cures Update until the EHR reporting period or performance period they have selected.

[30] For example, Use Security Labeling Services Available in Certified Health Information Technology (IT) for Electronic Health Record (EHR) Data to Facilitate Data Segmentation; Create and Implement a Plan to Improve Care for Lesbian, Gay, Bisexual, Transgender, and Queer Patients; Create and Implement a Language Access Plan; and COVID-19 Vaccine Promotion for Practice Staff.

Table 84 of the Proposed Rule (pg. 1230-1235) lists the objectives and measures for the PI performance category for the CY 2023 performance period/CY 2025 MIPS payment year as revised to reflect the proposed changes. In addition, Table 86 of the Proposed Rule (pg. 1238) reflects the proposed scoring methodology for the PI performance category for the performance period in CY 2023. Table 88 of the Proposed Rule (pg. 1240) reflects the PI performance category objectives with the 2015 Edition certification criteria. In addition, CMS proposes a voluntary reporting option for APM Entities to report the PI performance category at the APM Entity level beginning with the 2023 performance period

### MIPS Final Score Methodology and Calculation

For the CY 2023 performance period/2025 MIPS payment year, CMS intends to continue to build on the scoring methodology finalized for prior years. In the Proposed Rule, CMS proposes to amend the benchmarking policy to score administrative claims measures in the quality performance category using a benchmark calculated from performance period data; clarify the topped-out measure policy and update the topped-out measure life cycle for scoring topped-out measures in the quality performance category; and establish a maximum cost improvement score of 1 percentage point out of 100 percentage points available for the cost performance category beginning with the CY 2022 performance period/2024 MIPS payment year. In the Proposed Rule, regarding the calculation of the final score, CMS proposes several changes (e.g., facility-based MIPS eligible clinicians eligible to receive the complex patient bonus; virtual groups eligible for facility-based measurement, and changes to the definition of a facility-based MIPS eligible clinician) and includes an RFI regarding additional risk indicators and data sources (e.g., z-codes, indices) CMS may consider for the complex patient bonus formula. CMS provides a complete list of questions regarding this RFI in the Proposed Rule (pgs. 1273-1274), including information regarding terms like “safety net providers” and “essential community providers” in the context of the complex patient bonus.

#### MIPS Payment Adjustments

CMS uses a final score to determine MIPS payment adjustments. CMS proposes the performance threshold for the CY 2025 MIPS payment year would be the mean of the final scores for all MIPS eligible clinicians for the CY 2019 MIPS payment year, which is 75 points (rounded from 74.65 points). CMS requests comment on whether it should use data from alternative years to set the performance threshold for the CY 2025 MIPS payment year. Figure 4 of the Proposed Rule (pg. 1284) provides an illustrative example of MIPS payment adjustment factors based on final scores and proposed performance threshold for the 2025 MIPS payment year. The below table compares the 2024 MIPS payment year with the Proposed 2025 MIPS payment year based on the point system and associated adjustments.

| 2024 MIPS Payment Year | | 2025 MIPS Payment Year | |
|---|---|---|---|
| **Final Score Points** | **MIPS Adjustment** | **Final Score Points** | **MIPS Adjustment** |
| 0.0-18.75 | Negative 9% | 0.0-18.75 | Negative 9% |
| 18.76-74.99 | Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale | 18.76-74.99 | Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale |
| 75.0 | 0% adjustment | 75.0 | 0% adjustment |

| | | | |
|---|---|---|---|
| 75.01-88.99 | Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 75.00 to 100.00 This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. | 75.01-100 | Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 75.00 to 100.00 This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. |
| 89.0-100 | Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for final scores from 75.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 89.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance | | |

### Third Party Intermediaries General Requirements

In the CY 2022 PFS final rule, CMS finalized a policy indicating that MIPS data may be submitted on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or Alternative Payment Model (APM) Entity by any of the following third-party intermediaries: Qualified Clinical Data Registry (QCDR); qualified registry; health IT vendor; or CMS approved survey vendor. CMS also provided regulations to allow for QCDRs, qualified registries, health IT vendors, and CAHPS for MIPS survey vendors to support subgroup reporting which is an option for MIPS eligible clinicians reporting MIPS Value Pathways.

In the Proposed Rule, CMS proposes to update the definition of a third-party intermediary to include subgroups and APM Entities. In addition, CMS proposes additional requirements specific to QCDRs, as it believes QCDRs and QCDR measures can help further health equity through expanded data collection, reporting and analysis. As such, in the Proposed Rule, CMS proposes changes to clarify QCDR measure submission and approval processes. In addition, CMS proposes changes to corrective action plan (CAP) requirements, including requirements that the CAP require the third-party intermediary to notify certain parties of the impact via a communication plan.

Also, CMS proposes to add a new reason to terminate QCDRs beginning with the CY 2024 performance period. CMS proposes that if a QCDR submits a participation plan but does not submit MIPS data for the applicable performance period for which they self-nominated, it will be terminated.

Lastly, the Proposed Rule includes various RFIs. One RFI is on third party intermediary support of MVPs, where CMS notes concerns of allowing third party intermediaries to only support specific measures in an MVP, as it creates undue burden on the MVP Participant and

limits the clinicians' choice of measures available. In addition, CMS provides an RFI regarding national continuing medical education (CME) accreditation organizations submitting improvement activities, as CMS is considering approaches to include CME accreditation organizations as third-party intermediaries solely for this category. Similarly, in separate RFIs, CMS requests feedback on the value to clinicians for adding CME accreditation organizations as third-party intermediaries and potential criteria for selecting CME accreditation organizations should a new type of third-party intermediary be established.

### Public Reporting on the Compare Tools hosted by HHS

In the Proposed Rule, CMS notes that the Care Compare tool includes information on how beneficiaries may access care. To enhance the Care Compare tools, CMS proposes developing a telehealth indicator to help patients identify providers performing telehealth services and publicly reporting Medicare procedural utilization data. CMS also encourages stakeholder feedback by providing an RFI on ways to incorporate health equity into public reporting on doctor and clinician profile pages.

### APM Incentive Payment

Under the Quality Payment Program, an eligible clinician who is a Qualifying APM Participant (QP) for a performance year earns an APM Incentive Payment, which is made in the corresponding payment year for payment years 2019 through 2024. The APM Incentive Payment is equal to 5 percent of the eligible clinician's estimated aggregate payments for covered professional services in the base period. After performance year 2022 (payment year 2024), there is no further statutory authority for a 5 percent APM Incentive Payment for eligible clinicians who become QPs for a year.

CMS recognizes that the lack of financial incentives under the QPP for QPs for the 2023 performance year (2025 payment year) could reduce eligible clinicians' participation in Advanced APMs. Although CMS indicates that is has considered a range of potential administrative actions to address these concerns, it was concerned about making drastic changes to Advanced APMs. As such, CMS seeks public input as it considers potential options for the 2024 performance period and 2026 payment year of the QPP and potentially beyond.

### Advanced APMs

Any eligible clinicians that participate in an Advance APM and satisfy Qualifying APM Participant (QP) thresholds are excluded from the MIPS reporting requirements and payment adjustments. Advanced APMs are those that require "more than a nominal amount of financial risk" per statute. In 2017, CMS set the "more than nominal financial risk" threshold at 8% and set an expiration date of the 2024 performance year for the threshold. In the Proposed Rule, CMS considered whether the threshold needed to be changed. CMS proposes to make the 8% minimum permanent.

In addition, in the Proposed Rule CMS provides an RFI regarding a potential transition to individual QP determinations only, as opposed to determinations at the APM Entity group level. CMS requests public feedback on whether an individual level QP determination approach should be more carefully considered by CMS as a means to better identify and reward individual eligible clinicians with substantial engagement in Advanced APMs.

As required by law, a threshold for the level of participation in Advanced APMs is required for an eligible clinician to become a QP for a year. Table 92 of the Proposed Rule (pg. 1341) includes QP Threshold Score Updates.

### Continuing to Advance to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs - RFI

As noted in the CY 2022 PFS Final Rule, CMS aims to move fully to digital quality measurement in CMS quality reporting and value-based purchasing programs. As part of this effort, in the Proposed Rule, CMS issues an RFI regarding a potential refined definition of digital quality measures (dQMs), data standardization activities to leverage and advance standard for digital data and approaches to achieve FHIR® eCQM reporting. A complete list of questions in the RFI are provided in the Proposed Rule (pgs. 1117-1118).

### Advancing the Trusted Exchange Framework and Common Agreement (TEFCA) - RFI

CMS notes that in January 2022, ONC announced a significant TEFCA milestone, the release of TEFCA Version 1. In addition to other policy changes provided in the Proposed Rule related to interoperability, CMS indicates it is considering future opportunities to encourage information exchange under TEFCA for payment and operations activities such as submission of clinical documentation to support claims adjudication and prior authorization processes. In the Proposed Rule (pgs. 1122-1123), CMS provides various questions regarding user cases that could be enabled trough TEFCA, how TEFCA can help advance the goals of CMS programs, incentive options under TEFCA through CMS programs, and concerns about enabling exchange under TEFCA.

## What's Next?

CMS typically publishes the final PFS/QPP regulation in early November and the comment period closes on September 6, 2022. Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this proposed rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. Please direct your feedback to Jenna Stern, Associate Vice President, Regulatory Affairs and Public Policy, in Vizient's Washington, D.C. office.