# CY 2024 Medicare Physician Fee Schedule and Quality Payment Program Final Rule

On November 2, 2024, the Centers for Medicare and Medicaid Services (CMS) released the calendar year (CY) 2024 Medicare Physician Fee Schedule (MPFS) final rule. This final rule includes updates on policy changes for Medicare payments under the Fee Schedule, and other Medicare Part B issues, on or after **January 1, 2024**. CMS notes this final rule is one of several final rules that reflect a broader Administration-wide strategy to create a more equitable health care system that results in better access to care, quality, affordability, and innovation. For additional information please see CMS's CY 2024 MPFS Fact Sheet and CY 2024 Quality Payment Program Fact Sheet.

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## A. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (section II.D.)

**Finalized Changes**

- **Proposed Clarifications and Revisions to the Process for Considering Changes to the Medicare Telehealth Services List**

CMS finalized their revised review process to consider future requests to add services to, remove services from, or change the status of, services on the Medicare Telehealth Services List, beginning for the CY 2025 Medicare Telehealth Services List, which will include submissions received no later than February 10, 2024. The steps are as follows:

- Step 1: Determine whether the service is separately payable under the PFS.

- Step 2: Determine whether the service is subject to the provisions of section 1834(m) of the Act.
- Step 3: Review the elements of the service as described by the HCPCS code and determine whether each of them is capable of being furnished using an interactive telecommunications system.
- Step 4: Consider whether the service elements of the requested service map to the service elements of a service on the list that has a permanent status described in previous final rulemaking.
- Step 5: Consider whether there is evidence of clinical benefit analogous to the clinical benefit of the in-person service when the patient, who is located at a telehealth originating site, receives a service furnished by a physician or practitioner located at a distant site using an interactive telecommunications system.

CMS also finalized their proposal to assign "permanent" or "provisional" status to any services for which the service elements map to the service elements of a service on the list that has a permanent status described in previous final rulemaking or for which there is evidence of clinical benefit analogous to the clinical benefit of the in-person service when the service is furnished via telehealth by an eligible Medicare telehealth physician or practitioner.

- **Consolidation of the Categories for Services Currently on the Medicare Telehealth Services List**

For CY 2024, CMS finalized as proposed changes to redesignate any services that are currently on the Medicare Telehealth Services List on a Category 1 or 2 basis and would be on the list for CY 2024 to the new "permanent," category while any services currently added on a "temporary Category 2", or Category 3 basis would be assigned to the "provisional" category.

- **Implementation of Provisions of the Consolidated Appropriations Act (CAA), 2023**

CMS finalized the following provision of the CAA, 2023:

1. In-person Requirements for Mental Health Telehealth: CMS finalized as proposed the policy to delay in-person requirements for telehealth behavioral health services until January 1, 2025.
2. Originating Site Requirements: CMS finalized their proposal to temporarily expand telehealth originating sites to include the patient's home, for any non-mental health telehealth service on the Medicare Telehealth Services List through December 31, 2024.
3. Telehealth Practitioners: CMS finalized the proposal to add marriage and family therapists (MFTs) and mental health counselors (MHC) as distant site practitioners for purposes of furnishing telehealth services. CMS also finalized the proposed amendments to add MFTs and MHCs to the list of distant site practitioners.
4. Audio-Only Services: CMS finalized their proposal to continue to provide for coverage and payment of telehealth services via an audio-only communications system during the period beginning on the first day after the end of such emergency period and ending on December 31, 2024. This provision applies only to telehealth services specified on the Medicare Telehealth Services List that are permitted to be furnished via audio-only technology as of the date of enactment of the CAA, 2023.

- **Place of Service for Medicare Telehealth Services**

CMS finalized as proposed that beginning in CY 2024, claims for telehealth services billed with Place of Service (POS) 10 will be paid at the non-facility PFS rate. Claims billed with POS 02 will continue to be paid at the facility rate. In addition, CMS clarified that modifier '95' should be used when the clinician is in the hospital and the patient is in the home, as well as for outpatient therapy services furnished via telehealth.

- **Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations**

CMS finalized proposals to remove the telehealth frequency limitations for the following codes:

1. Subsequent Inpatient Visit CPT Codes: 99231, 99232, & 99233
2. Subsequent Nursing Facility Visit CPT Codes: 99307, 99308, 99309, & 99310

3. Critical Care Consultation Services: HCPCS Codes: G0508 & G0509

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

Direct Supervision via Use of Two-way Audio/Video Communications Technology: CMS finalized a provision to continue to define direct supervision to permit the immediate availability of the supervising practitioner through real-time audio and visual interactive telecommunications through December 31, 2024.

Clarifications for Remote Monitoring Services: (1) Data Collection Requirements: CMS finalized a proposal to clarify that the data collection minimums apply to existing RPM and RTM code families for CY 2024. The following remote monitoring codes currently depend on collection of no fewer than 16 days of data in a 30-day period, as defined and specified in the code descriptions: 98976, 98977, 98978, 98989, & 98981. (2) Use of RPM, RTM, in Conjunction with Other Services: CMS finalized a proposal to clarify that RPM and RTM may not be billed together, so that no time is counted twice by billing for concurrent RPM and RTM services. (3) Other Clarifications for Appropriate Billing: CMS finalized a proposal to clarify that, in circumstances where an individual beneficiary may receive a procedure or surgery, and related services, which are covered under a payment for a global period, RPM services or RTM services (but not both RPM and RTM services concurrently) may be furnished separately to the beneficiary, and the practitioner would receive payment for the RTM or RPM services, separate from the global service payment, so long as other requirements for the global service and any other service during the global period are met.

Telephone Evaluation and Management Services: CMS finalized a proposal to continue active payment status for CPT codes 98966 through 98968. These services will be available through the end of CY 2024.

- **Telehealth Originating Site Facility Fee Payment Amount Update**

For CY 2024, the final payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is $29.96. Table 12 of the final rule shows the Medicare telehealth originating site facility fee and the corresponding MEI percentage increase for each applicable time period.

- **Payment for Outpatient Therapy Services, Diabetes Self-Management Training, and Medical Nutrition Therapy when Furnished by Institutional Staff to Beneficiaries in Their Homes Through Communication Technology**

CMS finalized a proposal to continue to allow institutional providers to bill for these services when furnished remotely in the same manner they have during the PHE for COVID-19 through the end of CY 2024 with one amendment for modifiers, to allow outpatient hospitals and other providers of physical therapy, occupational therapy, and speech-language pathology, DSMT and MNT services that remain on the Medicare Telehealth Services List for CY 2024 to bill for these services when furnished remotely in the same way they have been during the COVID-19 PHE and through the end of CY 2023, including that for hospitals, beneficiaries' homes will no longer need to be registered as provider-based departments of the hospital to allow for hospitals to bill for these services.

**Background/Rationale**

- **Proposed Clarifications and Revisions to the Process for Considering Changes to the Medicare Telehealth Services List**

Between CY 2020 and CY 2023, many services were added to the Medicare Telehealth List on a temporary basis during the COVID-19 Public Health Emergency (PHE) on a Category 3 basis. Now that the COVID-19 PHE has ended, CMS finalized changes to clarify and modify processes for considering changes to the Medicare Telehealth Services List. When reviewing submissions during the PHE, in the absence of evidence supporting clinical benefit, but public comment expressing support for possible clinical benefit, CMS generally accepted a temporary addition to the Medicare Telehealth Services list, allowing more time for evidence generation.

- **Consolidation of the Categories for Services Currently on the Medicare Telehealth Services List**

CMS believes the redesignations in this calendar year help ease confusion in future years, including in the event of subsequent legislation regarding Medicare telehealth services. Furthermore, for a code that receives provisional status, as evidence generation builds, CMS may grant the code a permanent status in a future year or remove the service from the list in the interest of patient safety based on findings

from ongoing monitoring of telehealth services within CMS and informed by publicly available information. The proposal did not set any specific timing for reevaluation of services added to the Medicare Telehealth Services List on a provisional basis because evidence generation may not align with a specific timeframe. CMS would not assign provisional status when it is improbable that the code would ever achieve permanent status. Overall, commenters expressed support for the proposal.

Table 11 of the final rule lists codes CMS finalized for the Medicare Telehealth Services List and includes the simplified categorization of each service as either provisional or permanent.

- **Implementation of Provisions of the CAA, 2023**

CMS finalized the following provision of the CAA, 2023:

1. In-person Requirements for Mental Health Telehealth: Some commenters supported the proposal to extend the delay of in-person requirements for mental health telehealth. Some commenters highlighted that recent data suggest that even in complex patients with significant behavioral health issues, virtual-only care does not result in worse outcomes. However, CMS reminded commenters they are only revising the regulations to conform to the requirements in section 4113(d) of section FF, title IV, Subtitle B of the CAA, 2023. Commenters also suggested that CMS should implement the in-person requirements when the delay mandated by the CAA, 2023 expires. CMS stated that the statutory requirements directed them otherwise.
2. Originating Site Requirements: Commenters expressed concerns regarding the expiring flexibility for telehealth practitioners to use their currently enrolled location instead of their home address when providing services from their home. Stakeholders suggested that expiration of this flexibility poses a potential and imminent threat to public safety.

- **Place of Services for Medicare Telehealth Services**

CMS clarified that telehealth services that are not furnished in the patient's home will continue to be furnished in the same types of originating sites in which they were

furnished prior to the PHE, such as hospitals or rural health clinics; therefore, the resource costs associated with these services will resemble those of services furnished in person in a facility setting as they did prior to the PHE.

- **Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations**

CMS believes that continuing to suspend these frequency limitations on a temporary basis for CY 2024 will allow more time to continue to evaluate patient safety while preserving access in a way that is not disruptive to practice patterns that were established during the PHE.

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

Direct Supervision via Use of Two-way Audio/Video Communications Technology: CMS believes that it is appropriate to continue to permit direct supervision via virtual means using audio/video real-time communications technology through the end of CY 2024 given that many telehealth flexibilities adopted to address the PHE for COVID-19 are set to expire under the statute following this time period. CMS also sought comments to help inform consideration of how virtual services could be furnished in all residency training locations beyond December 31, 2024, to include what other clinical treatment situations are appropriate to permit the virtual presence of the teaching physician. CMS chose not to extend this policy to include in-person services furnished by residents at this time.

Clarifications for Remote Monitoring Services: CMS offered stakeholders additional clarifications regarding the new patient requirement and that RPM, not RTM, services require an established patient relationship after the end of the PHE. While CMS has not specified in rulemaking whether the RTM services require an established patient relationship, CMS believes that similar to RPM, such services would be furnished to a patient after a treatment plan had been established. CMS also further clarifies that the policy that prohibits RPM or RTM services being furnished during the global period only applies to billing practitioners who are receiving the global service payment.

Telephone Evaluation and Management Services: Commenters were supportive of the proposal and stated that these services are a critical component of how care is

provided to patients and are particularly valuable in connecting with patients living in rural areas where regular internet connection and/or cellular reception may be entirely unavailable or unreliable.

- **Payment for Outpatient Therapy Services, Diabetes Self-Management Training, and Medical Nutrition Therapy when Furnished by Institutional Staff to Beneficiaries in Their Homes Through Communication Technology**

Commenters requested that CMS provide additional clarity on how institutional providers should bill for these services in CY 2024, including the specific use of modifiers. In response, CMS stated that the billing policy for CY 2024 will reflect the online billing policy for CY 2023. However, with respect to the use of modifiers, CMS clarified that for services furnished beginning in CY 2024 that they require the use of the 95 modifier to be applied to claims from outpatient hospitals, as soon as hospitals can update their systems — in addition to the continued use of the 95 modifier for outpatient therapy services discussed above for all other institutional providers furnishing outpatient therapy services via telehealth under Part B. Although CMS did not receive comments specifically from CAHs electing Method II, these CAHs will continue their longstanding practice of using the GT/GQ modifier, as appropriate.

**Comments:**

- **Implementation of the Provisions of the CAA, 2023**

CMS requested comments on the following provisions:

1. Originating Site Requirements: CMS requests further information from interested parties to better understand the scope of considerations involved with including a practitioner's home address as an enrolled practice location when that address is the distant site location where they furnish Medicare telehealth services.

- **Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations**

CMS requests further information from interested parties on how practitioners have been ensuring that Medicare beneficiaries receive subsequent inpatient and nursing

facility visits, as well as critical care consultation services since the expiration of the PHE.

## B. Valuation of Specific Codes (section II.E.)

**Finalized Changes**

- **General Behavioral Health Integration Care Management** (CPT code 99484 and HCPCS code G0323)

CMS finalized as proposed the increase in the work Relative Value Unit (RVU) for the General Behavioral Health Integration Care Management CPT code 99484 and HCPCS code G0323 from 0.61 to 0.93 and increase the work time to 21 minutes. They are also finalizing the practice expense (PE) inputs as recommended by the Relative Value Scale Update Committee (RUC) without refinement and applying the same changes to the HCPCS code G0323.

- **Payment for Caregiver Training Services (CTS)**

CMS finalized a revised definition of caregiver to be "an adult family member or other individual who has a significant relationship with, and who provides a broad range of assistance to, an individual with a chronic or other health condition, disability, or functional limitation" and "a family member, friend, or neighbor who provides unpaid assistance to a person with a chronic illness or disabling condition".

CMS revised the caregiver definition to incorporate a broader definition that was previously established in the Recognize, Assist, Include, Support, and Engage (RAISE) Family Caregivers Act.

CMS finalized the work RVUs and direct PE inputs for CPT codes 96202, 96203, 97550, 97551, and 97552 as proposed.

**Background/Rationale**

- **General Behavioral Health Integration Care Management**

CMS generally received positive feedback on the proposed payment increases for general behavioral health integration services. CMS noted that some commenters recommended developing a code for 20 additional minutes of care management

services and invites the public to submit a nomination for that code per the official nomination process outlined in section II.C. of the rule.

- **Payment for Caregiver Training Services (CTS)**

Numerous commented disagreed with the caregiver definition as proposed by CMS for these services. While several alternatives were proposed, an overwhelming number recommended that CMS adopt the definition used by the Recognize, Assist, Include, Support, and Engage (RAISE) Family Caregivers Act. CMS recognized that the RAISE Family Caregivers Act is more expansive than the definition originally proposed but does not contradict it. Therefore, they elected to finalize the definition to incorporate both descriptions.

CMS received many comments in support of allowing a practitioner to provide CTS to a patient's caregiver(s) in multiple sessions, more than once per year. Some commenters also recommended limiting CTS to providers with longitudinal relationships to the patient. CMS agreed with these comments and clarified that the number of CTS sessions should be determined by the provider based on the patient's treatment plan, diagnosis, changes in condition, or their caregivers.

## C. Evaluation and Management Visits (section II.F.)

**Finalized Changes**

- **Office/Outpatient (O/O) E/M Visit Complexity Add-on Implementation**

CMS finalized the implementation of a separate add-on payment for HCPCS code G2211, that is expected to better recognize the resource costs associated with evaluation and management visits for primary care and longitudinal care. This code will be effective January 1, 2024. CMS is finalizing that the add-on code cannot be billed with an office or outpatient evaluation and management visit that is itself focused on a procedure or other service instead of being focused on longitudinal care for all needed healthcare services, or a single, serious or complex condition.

- **Split (or Shared) Visits**

CMS finalized their proposal to delay the implementation of the "substantive portion" as more than half of the total time through at least December 31, 2024. For CY 2024, CMS also finalized a revision to their definition of "substantive portion" of a split (or shared) visit to include the revisions to the Current Procedural Terminology (CPT) guidelines, such that for Medicare billing purposes, the "substantive portion" means more than half of the total time spent by the physician or nonphysician practitioner (NPP) performing the split (or shared) visit, or a substantive part of the medical decision making (MDM).

**Background/Rationale**

- **Office/Outpatient (O/O) E/M Visit Complexity Add-on Implementation**

CMS noted that implementing payment for this add-on code has redistributive impacts for all other CY 2024 payments under the MPFS, due to statutory budget neutrality requirements. Based on feedback from stakeholders, CMS finalized refinements to their proposed policy regarding their utilization assumptions and the estimated redistributive impact of the code on MPFS payments. These changes have reduced the estimated redistributive impacts by nearly one third from the estimated impact described in the CY 2021 MPFS final rule.

- **Split (or Shared) Visits**

CMS stated that they are finalizing this policy for CY 2024, in part, to avoid the administrative burden, as described by commenters, that would otherwise be present for facilities and practices that spend time and resources preparing for potential policy changes that are delayed year after year.

CMS noted that after reviewing the revisions made by the AMA CPT Editorial Panel that were included in the 2024 CPT codebook publication, specifically the E/M Services Guidelines language surrounding "substantive portion" for split (or shared) services, and in light of public comments in response to their policies, the Agency agreed that they should align their definition of substantive portion with the CPT E/M guidelines for this service. Although they continue to believe there can be instances where MDM is not easily attributed to a single physician or NPP when the work is shared, they expect that whoever performs the MDM and subsequently bills the visit would appropriately document the MDM in the medical record to support billing of the visit.

## D. Supervision of Outpatient Therapy Services, KX Modifier Thresholds, Diabetes Self-Management Training (DSMT) Services by Registered Dietitians and Nutrition Professional, and DSMT Telehealth Services (section II.I.)

**Finalized Changes**

- **Supervision of Outpatient Therapy Services in Private Practices**

CMS finalized their proposal to retain the Occupational Therapists in Private Practices (OTPP) and Physical Therapists in Private Practice (PTPP) direct supervision requirement for unenrolled PTs or OTs by clarifying that the remote therapeutic monitoring (RTM) general supervision regulation at §§ 410.59(c)(2) and 410.60(c)(2) applies only to the occupational therapy assistants (OTAs) and physical therapist assistants (PTAs) and does not include the unenrolled occupational therapists (OTs) and physical therapists (PTs). CMS finalized the amendments to the corresponding regulation text at §§ 410.59 and 410.60 as proposed. The finalized changes are consistent with the initial proposal.

- **Diabetes Self-Management Training (DSMT) Services Furnished by Registered Dietitians (RDs) and Nutrition Professionals**

CMS finalized their proposal to amend the regulation at § 410.72(d) to clarify that RDs and nutrition professionals must personally perform Medical Nutrition Therapy (MNT) services. They also finalized the clarification that an RD or nutrition professional may bill for, or on behalf of, the entire DSMT entity as the DSMT certified provider regardless of which professional furnishes the actual education services. Additionally, CMS finalizes the proposal to clarify § 410.72(d) to provide that, except for DSMT services furnished as, or on behalf of, an accredited DSMT entity, registered dietitians and nutrition professionals can be paid for their professional MNT services only when the services have been directly performed by them. The finalized changes were the same as CMS initially proposed.

- **DSMT Telehealth Issues (Distant Site Practitioners)**

CMS finalized their proposal to codify billing rules for DSMT services furnished as Medicare telehealth services at § 410.78(b)(2)(x) to allow distant site practitioners who

can appropriately report DSMT services furnished in person by the DSMT entity, such as RDs and nutrition professionals, physicians, nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs), to also report DSMT services furnished via telehealth by the DSMT entity, including when the services are performed by others as part of the DSMT entity. The finalized changes were the same as CMS initially proposed.

- **DSMT Telehealth Issues (Telehealth Injection Training for Insulin-Dependent Beneficiaries)**

CMS revised their initial proposal on insulin injection training and finalized that instead of allowing the 1 hour of in-person training (for initial and/or follow-up training), the full initial 10 hours, or annual 2 hours, of DSMT services for insulin-dependent diabetics, via telehealth, when clinically appropriate, will be allowed. This change will be reflected in the Medicare Claims Processing Manual, chapter 12, section 190.3. 6 – Payment for Diabetes Self-Management Training (DSMT) as a Telehealth Service through their change management system. Additionally, CMS finalized their proposed regulatory text with a modification that replaces the term "report" with "bill for" so that the new text for §410.78(b)(2)(x) will provide that any distant site practitioner who can appropriately bill for diabetes self-management training services may do so on behalf of others who personally furnish the services as part of the DSMT entity.

**Background/Rationale**

- **Supervision of Outpatient Therapy Services in Private Practices**

CMS finalized the proposed change in response to supportive stakeholder comments. CMS believes that this finalization may increase access to remotely provided series performed by PTAs and OTAs under the general supervision of PTPPs and OTPPs. The changes align the regulatory text at §§ 410.59 and 410.60 with the general supervision policy that was finalized for RTM services in the CY 2023 PFS final rule.

- **Diabetes Self-Management Training (DSMT) Services Furnished by Registered Dietitians (RDs) and Nutrition Professionals**

CMS finalized the proposed change in response to supportive stakeholder comments. CMS believes that this finalization may alleviate confusion regarding the wording of § 410.72(d), specifically regarding whether RD or nutrition professionals must personally

provide DSMT services. In response to one comment, CMS clarified that the professionals listed in the proposed clarification were purposely chosen, due to their recognition by the National Standards quality standards.

- **DSMT Telehealth Issues (Distant Site Practitioners)**

CMS believes that this finalization may increase access to DSMT telehealth services for Medicare beneficiaries in cases where the DSMT service is provided in accordance with the NSDSMEP quality standards.

- **DSMT Telehealth Issues (Telehealth Injection Training for Insulin-Dependent Beneficiaries)**

CMS received comments expressing concerns about the regulatory text for § 410.78(b)(2)(x) and the term distant site practitioner, not including outpatient hospitals, that bill on a UB-04 claim form using their NPI rather than a personal provider NPI, and pharmacies that enroll as suppliers of DSMT services. The commenters requested the term "approved entity" be included in the regulatory text. Additionally, commenters requested that the term "report" be changed to "bill for." As a result, CMS modified the regulatory text to read as follows: Any distant site practitioner or approved entity who/that can bill for diabetes self-management training services may do so on behalf of others who personally furnish the services as part of the DSMT entity.

## E. Advancing Access to Behavioral Health (section II.J.)

**Finalized Changes**

- **Implementation of Section 4121(a) of the CAA, 2023**

CMS finalized the definition of a marriage and family therapist (MFT) at § 410.53 as an individual possessing a master's or doctor's degree that meets the licensure or certification requirements for MFTs according to the state law where the services are provided. Additionally, the individual should have completed at least 2 years or 3,000 hours of post-master's degree clinical supervised experience in marriage and family therapy in settings such as hospitals, skilled nursing facilities (SNFs), private practices,

or clinics. Furthermore, the individual must hold a valid license or certification as an MFT in the state where the services are performed.

CMS finalized the definition of MFT services covered under the Medicare Part B benefit category at § 410.53(b)(1) as those provided by a MFT for the diagnosis and treatment of mental illnesses, where services must be of a type that would be covered if they were provided by a physician or as an incident to a physician's professional service, and at § 410.53(b)(2) excludes services provided to inpatients of a Medicare-participating hospital.

CMS finalized the definition of a mental health counselor (MHC) at § 410.54 as an individual holding a master's or doctor's degree that qualifies for licensure or certification as a mental health counselor, clinical professional counselor, or professional counselor according to the state law of the state where the services are provided. Additionally, the individual should have completed at least 2 years or 3,000 hours of post-master's degree clinical supervised experience in mental health counseling in settings such as hospitals, skilled nursing facilities, private practices, or clinics. Furthermore, the individual must hold a valid license or certification as an MHC, clinical professional counselor, or professional counselor in the state where the services are performed.

CMS finalized the definition of MHC services covered under the Medicare Part B benefit category at § 410.54(b)(1) as services provided by a MHC for the diagnosis and treatment of mental illnesses, where services must be of a type that would be covered if they were provided by a physician or as an incident to a physician's professional service, and at §410.54(b)(2) excludes services provided to inpatients of a Medicare-participating hospital.

CMS finalized an amendment to §405.400, which includes MFTs and MHCs as practitioners who may opt out of Medicare.

- **Inclusion of MFT and MHC into Existing Regulation**

CMS finalized amending § 410.10 to add MFT and MHC services to the list of included medical and other health services and amending § 410.150 to add MFTs and MHCs to the list of individuals or entities to whom payment is made.

CMS finalized amending § 410.32(a)(2) to add MFTs and MHCs to the list of practitioners who may order diagnostic tests.

CMS finalized codifying in a new § 414.53 the payment amounts authorized for MFT, MHC, and clinical social worker (CSW) services, where payment amount for CSW, MFT, and MHC services would be 80% of the lesser of the actual charge for the services or 75% of the amount determined for clinical psychologist services under the Physician Fee Schedule (PFS).

CMS finalized adding MFTs and MHCs to the list of practitioners eligible to provide Medicare telehealth services at the distant site and allowing Addiction Counselors who meet specific requirements to enroll in Medicare as MHCs.

CMS finalized that the term "mental health" includes the diagnosis and treatment of substance use disorders which applies to MFTs, MHCs, CSWs, and clinical psychologists (CPs) as part of their respective definitions and services.

- **Coding Updates to Allow MFT and MHC Billing**

CMS finalized the code descriptor for HCPCS code G0323 as follows: "Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist, clinical social worker, mental health counselor, or marriage and family therapist time, per calendar month." to enable MFTs, MHCs, CPs, and CSWs to bill for monthly care integration services.

CMS finalized conforming updates to the valuation of work and practice expense (PE) inputs for HCPCS code G0323 to align with the proposed changes to the valuation of CPT code 99484, which describes General Behavioral Health Integration.

- **Medicare Enrollment of MFTs and MHCs**

CMS finalized that MFTs and MHCs Medicare enrollment involve completing and submitting the appropriate Form CMS-855 application to the assigned Medicare Administrative Contractor (MAC). And MFTs and MHCs be subject to limited-risk screening, following the provisions outlined in § 424.518 where MFTs and MHCs meeting the finalized requirements in §§ 410.53 and 410.54 utilize the Form CMS-855I application to enroll in Medicare.

- **Implementation of Section 4132 of the CAA, 2023**

CMS finalized the creation of two new G-codes, G0017 and G0018, to describe psychotherapy for crisis services rendered in any applicable site of service where the non-facility rate for these services is applicable, excluding office settings, and proposes that these codes can be billed when the services are provided in any non-facility place of service except the physician's office setting.

CMS finalized establishing a fee schedule amount for the two new G-codes, G0017 and G0018, which corresponds to 150% of the current non-facility Relative Value Units (RVUs) for CPT codes 90839 and 90840 and suggests excluding expected expenditures for the new G-codes, G0017 and G0018, from the budget neutrality calculation for the CY 2024 PFS ratesetting.

- **Health Behavior Assessment and Intervention (HBAI) Services**

CMS finalized allowing CSWs, MFTs, and MHCs to bill for HBAI services described by CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168, and any successor codes, in addition to CPs, where Medicare payment for HBAI services is contingent upon their medical necessity and their contribution to the diagnosis, treatment, or improvement of a patient's condition.

- **Adjustments to Payment for Timed Behavioral Health Services**

CMS finalized applying 19.1 percent increase to the work Relative Value Units (RVUs) for psychotherapy codes billed under the Medicare Physician Fee Schedule (PFS). This adjustment will be implemented over a 4-year transition period to allow for a gradual change. A 19.1 increase will also be applied to the psychotherapy codes that are billed as an add-on to an E/M visit (CPT codes 90833, 90836, and 90838), and the codes describing HBAI services (CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168).

- **Updates to the Payment Rate for the PFS Substance Use Disorder (SUD) bundle (HCPCS codes G2086-G2088)**

CMS finalized increasing the current payment rate for HCPCS codes G2086 and G2087 to reflect two individual psychotherapy sessions per month, based on a crosswalk to the work RVUs assigned to CPT code 90834 (Psychotherapy, 45 minutes with patient), rather than CPT code 90832 (Psychotherapy, 30 minutes with patient), adding 1.08 RVUs to the work value assigned to HCPCS codes G2086 and G2087,

which results in a new work RVU of 8.14 for HCPCS code G2086 and 7.97 for HCPCS code G2087, and updating the work RVUs assigned to CPT code 90834 to 2.35.

**Background/Rationale**

- **Implementation of Section 4121(a) of the Consolidated Appropriations Act, 2023**

CMS finalized regulatory changes to comply with the CAA), 2023 which expanded Medicare coverage and payment for MFTs and MHCs services under Part B of the Medicare program. CMS believes that these changes will advance health equity by enhancing access to behavioral health services for Medicare beneficiaries. CMS clarified that the statutory benefit category for MFTs and MHCs does not prohibit them from delivering services to hospital inpatients, noting that payment for MFT and MHC services to hospital inpatients will be made under the hospital inpatient prospective payment system as "hospital inpatient services," in accordance with section 1861(b) of the Act.

CMS believes that the finalized requirement for MFTs and MHCs to have a minimum of 2 years or 3,000 hours of post-master's degree clinical supervised experience aligns with state licensure requirements. CMS clarifies that clinical supervised experience earned after obtaining the required degree and licensure can be considered for the 2 years of clinical supervised experience required for Medicare enrollment for MFTs or MHCs. CMS also notes that the 2 years or 3,000 hours of clinical supervised experience required for Medicare enrollment is a total requirement, without specifying the number of hours required for direct client contact, deferring to State law and licensure requirements.

- **Inclusion of MFT and MHC into Existing Regulation**

CMS finalized regulatory changes to comply with the CAA, 2023, including marriage and family therapists and mental health counselors as part of the implementation of section 4121.

While CMS received some comments expressing concern regarding the statutory requirement that MFTs and MHCs be paid at 75 percent of the fee schedule rate, CMS clarified that the payment determination is specified in section 1833(a)(1)(FF) of the

Act, indicating that, for MFT services and MHC services under section 1861(s)(2)(II) of the Act, the amounts paid will be 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for payment of a psychologist.

CMS finalized the proposal to allow addiction counselors meeting all applicable requirements of a MHC to enroll in Medicare as MHCs, recognizing that some states certify addiction counselors with a bachelor's degree, but for Medicare purposes, individuals must possess a master's or doctor's degree to qualify as MHCs, as defined in section 1861(III)(4)(A) of the Act and § 410.54.

CMS elected not to finalize changes to the regulation text at § 410.54 to reference addiction counselors specifically, clarifying that despite the lack of specific regulatory changes, alcohol and drug counselors providing addiction counseling services for the diagnosis and treatment of mental illnesses, including substance use disorders, can enroll in Medicare and bill as MHCs if they meet all statutory requirements related to education, clinical supervised experience, and licensure.

- **Coding Updates to Allow MFT and MHC Billing**

While CMS received some comments encouraging CMS to ensure that MFTs and MHCs are able to provide services and bill for them using applicable HCPCS codes even if the code descriptors do not address the provider types eligible to bill for these services, CMS clarified that MFTs and MHCs can provide services and bill for them using applicable HCPCS codes even if the code descriptors do not explicitly mention the eligible provider types.

In response to comments requesting clarification that MHC and MFT services are excluded from payment under the OPPS, CMS notes that because MHC and MFT services are professional services of nonphysician practitioners paid under the PFS, they must be excluded from payment under the OPPS, effective January 1, 2024. In addition, CMS anticipates amending the regulation at § 419.22 to explicitly exclude the services of MFTs and MHCs from payment under the OPPS, with new paragraphs (w) and (x) added, respectively. In response to comments, CMS finalized amending the regulation at § 410.27 to revise the definition of "nonphysician practitioner" to explicitly include MFTs and MHCs for therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service.

- **Medicare Enrollment of MFTs and MHCs**

CMS finalized that MFT and MHC supplier types undergo limited-risk screening under § 424.518, due to the absence of any justification to categorize these suppliers differently and assign them to a higher screening category compared to other non-physician practitioner types.

- **Implementation of Section 4132 of the CAA, 2023**

In response to numerous comments regarding psychotherapy being out of the scope of practice for peer support specialists, CMS clarified that peer support specialists participating in furnishing any service as auxiliary personnel, including psychotherapy for crisis, must operate within the scope of their role and adhere to any applicable state requirements, including licensure, and affirmed that the regulatory definition of auxiliary personnel at § 410.26 does not propose to specify any particular types of personnel.

- **Health Behavior Assessment and Intervention (HBAI) Services**

CMS recognizes that CSWs, MFTs, and MHCs have the education and training to address psychosocial barriers and can play a vital role in multidisciplinary patient care, particularly for patients with physical health conditions.

- **Adjustments to Payment for Timed Behavioral Health Services**

CMS stated that the increases recognize potential changes in the complexity of care for beneficiaries and addresses concerns about relative undervaluation of work estimates, and their intent to maintain consistency and avoid anomalies throughout the 4-year transition period for the increase in work RVUs for add-on psychotherapy codes.

- **Updates to the Payment Rate for the PFS Substance Use Disorder (SUD) bundle (HCPCS codes G2086-G2088)**

CMS finalized increasing the payment rate for HCPCS codes G2086 and G2087, reflecting two individual psychotherapy sessions per month for office-based SUD services, based on a crosswalk to the work RVUs assigned to CPT code 90834 (Psychotherapy, 45 minutes with patient), rather than CPT code 90832

(Psychotherapy, 30 minutes with patient). CMS noted that the proposed increase more accurately captures the cost, time, and effort involved in delivering these services. This adjustment aims to ensure beneficiaries have access to a comprehensive range of services, particularly in light of the drug overdose epidemic referenced in the comments.

**Comments:**

- **Inclusion of MFT and MHC into Existing Regulation**

CMS welcomes additional information regarding the valuation of services furnished by MFTs and MHCs for future consideration.

- **Adjustments to Payment for Timed Behavioral Health Services**

CMS welcomes additional feedback on the valuation of psychological and neuropsychological testing services.

## F. Proposals on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Medical Services (section II.K.)

**Finalized Changes**

- **Dental Services Inextricably Linked to Chemotherapy Services When Used in the Treatment of Cancer**

CMS finalized amendments to § 411.15(i)(3)(i) to add chemotherapy in the treatment of cancer as an additional example of a clinical scenario under which payment can be made under Medicare Parts A and B, under the applicable payment system, for certain dental services that occur within the inpatient hospital and outpatient setting, as clinically appropriate. CMS added dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, chemotherapy in the treatment of cancer to the list of examples of dental services that are not subject to the exclusion under section 1862(a)(12) of the Act and for which payment can be made under Medicare Parts A and B for dental services. The finalized changes were the same as CMS initially proposed.

- **Dental Services Inextricably Linked to CAR T-Cell Therapy, When Used in the Treatment of Cancer**

CMS finalized, with modifications, an amendment to § 411.15(i)(3)(i) to add dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with CAR T-cell therapy in the treatment of cancer to the list of examples of services that are not subject to the exclusion under section 1862(a)(12) of the Act and for which payment can be made under Medicare Parts A and B. CMS further note that the finalized policies outlined in this section of this final rule would not prevent a MAC from determining on a case-by-case basis that payment can be made for certain dental services in other circumstances not specifically addressed within this final rule and § 411.15(i)(3)(i), including as that regulation is amended by this final rule. The finalized changes were the same as CMS initially proposed.

- **Dental Services Inextricably Linked to the Administration of High-Dose Bone-Modifying Agents (antiresorptive therapy) When used in the Treatment of Cancer**

CMS finalized amendments to § 411.15(i)(3)(i) to provide that dental services that are inextricably linked to, and substantially related and integral to the clinical success of, the administration of high-dose bone-modifying agents (antiresorptive therapy) in the treatment of cancer are not subject to the exclusion under section 1862(a)(12) of the Act; and that payment can be made under Medicare Parts A and B, under the applicable payment system, for such dental services that occur within the inpatient hospital and outpatient setting, as clinically appropriate. CMS also finalized an amendment to § 411.15(i)(3)(i) to add dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with the administration of high-dose bone-modifying agents (antiresorptive therapy) in the treatment of cancer to the list of examples of services that are not subject to the exclusion under section 1862(a)(12) of the Act and for which payment can be made under Medicare Parts A and B. The finalized changes were the same as CMS initially proposed.

- **Proposed Amendments to Regulations Regarding Dental Services Inextricably Linked to Treatment for Head and Neck Cancer**

CMS finalized the proposal that Medicare Part A and Part B payment can be made for certain dental services when furnished prior to or contemporaneously with the treatment of head and neck cancer and for certain dental services furnished before or during single modality radiation therapy when used in the treatment of head and neck cancer even when used as the single treatment modality and not in combination with any other therapy types.

While CMS did not initially propose to add to the regulation that Medicare Parts A and B payment is permitted for medically necessary diagnostic and treatment services to address dental or oral complications after radiation, chemotherapy, and/or surgery when used in the treatment of head and neck cancer, CMS was persuaded by evidence provided by commenters that treatment for head and neck cancer uniquely causes additional significant and acute (developing during active treatment) dental and/or oral complications for the patient, including increased risk of infection even after the direct treatment for head and neck cancer has ended. Therefore, CMS clarified that for the purposes of treatment for head and neck cancer, treatment may include dental services required in the period following direct treatment for the head and neck cancer.

**Background/Rationale**

- **Dental Services Inextricably Linked to Chemotherapy Services When Used in the Treatment of Cancer**

CMS received comments expressing the view that payment for dental services in the proposed additional circumstances could improve patient outcomes and quality of life and reduce Medicare expenditures overall by avoiding the need to cover medical complications arising from untreated dental conditions. CMS agreed with commenters that there is evidence to support that certain dental services serve to mitigate the substantial risk to the clinical success of the medical services such as chemotherapy due to the severity of complications that can be caused by the dental infection. In addition, administering chemotherapy before providing dental treatment when an identifiable oral or dental infection is present does not align with the

established standard of care, and that the dental services are considered to be an essential clinical requirement before moving forward with the primary medical procedure.

- **Dental Services Inextricably Linked to CAR T-Cell Therapy, When Used in the Treatment of Cancer**

CMS agreed with commenters that CAR T-cell therapy causes immunosuppression, which may lead to significant oral complications and adverse events, including the possibility of an oral or dental infection, which in turn leads to serious and imminent risks to the success of the primary medical procedures and treatments. CMS believes that proceeding without a dental or oral exam and necessary diagnosis and treatment of any presenting infection of the mouth prior to (CAR) T-cell therapy when used in the treatment of cancer could lead to systemic infection or sepsis, as well as other complications for the patient.

- **Proposed Amendments to Regulations Regarding Dental Services Inextricably Linked to Treatment for Head and Neck Cancer**

CMS agreed with commenters that the treatment of head and neck cancer causes oral complications caused by the primary medical treatment itself and increases the risk of infection after the direct treatment. Treatments for head and neck cancers are demonstrated to cause infection, caries, mucositis, and osteoradionecrosis, among other complications and jeopardize successful outcomes for the treatments. As a result, CMS believes the provision of dental services in the context of treatments for head and neck cancers for the complications of the medical treatment is inextricably linked to the primary medical treatment.

In addition, the commenters brought up evidence that these complications from the treatment for head and neck cancer may occur after some passage of time following the primary medical treatment. In other words, the treatment of head and neck cancer directly causes oral complications, which may emerge after the treatment is completed. Therefore, CMS added to the proposed changes, addressing that there is a direct connection between the primary treatment and the dental and oral complications caused by the treatment for head and neck cancer itself, including those that occur after the direct treatments for cancer.

**Comments:**

- **Proposed Amendments to Regulations Regarding Dental Services Inextricably Linked to Treatment for Head and Neck Cancer**

CMS continued to seek feedback from the public and interested parties on our continued interest in understanding how the timing of medical treatment and oral health care might illustrate an inextricable linkage.

## G. Drugs and Biological Products Paid Under Medicare Part B (section III.A.)

**Finalized Changes**

- **Provisions from the Inflation Reduction Act Relating to Drugs and Biologicals Payable Under Part B**

Payment for Drugs under Medicare Part B During an Initial Period

To meet statutory requirement of section 11402 of the IRA, new biosimilars that are used after July 1, 2024, will be subject to a maximum payment of wholesale acquisition cost (WAC) plus 3 percent until the average sale price (ASP) becomes available. This is consistent with prior regulation and the Sustaining Excellence in Medicaid Act of 2019. CMS finalized their proposal to codify WAC based changes to Section 1847A(c)(4) of the Act in § 414.904 by revising the regulatory text for WAC-based payment limits before January 1, 2019, and after January 1, 2019, as well as new biosimilars used after June 30, 2024 during the initial phase when ASP is unavailable.

Temporary Increase in Medicare Part B Payment for Certain Biosimilar Biological Products.

CMS finalized the definitions of "applicable 5-year period" and "qualifying biosimilar biological product" at § 414.902 to align the regulatory definition with section 11403 of the IRA. Qualifying biosimilars would be those which have ASP less than their reference biologic, and an applicable 5-year period will start on October 1, 2022 and end on December 31, 2027. During the applicable 5-year period, qualifying biosimilar biologic products will receive ASP plus 8 percent reimbursement, which will be higher than the payments received by their reference biologics (i.e., ASP plus 6 percent).

Inflation-Adjusted Beneficiary Coinsurance and Medicare Payment for Medicare Part B Rebatable Drugs.

CMS finalized addition of the inflation-adjusted coinsurance amount in § 489.30, to reflect statutory requirements outlined in 1847A(i)(5) of the IRA. This would establish the calendar quarter inflation-adjusted ASP for drugs whose ASP exceeds the rate of inflation. CMS also codified the payments for such Part B drugs would be the difference between the payment amount and the inflation-adjusted coinsurance amount after accounting for deductible and sequestration.

Limitations on Monthly Coinsurance and Adjustments to Supplier Payment Under Medicare Part B for Insulin Furnished Through Durable Medical Equipment

The IRA requires that insulin used through durable medical equipment (DME) by a beneficiary may not be subject to the Part B deductible, and must not have a monthly coinsurance that exceeds $35. It also specifies that Medicare must pay the difference between the 20% coinsurance and the $35 limit, should a difference exist. CMS finalized codification of all these elements. Specifically, § 489.30 is amended to reflect the monthly coinsurance limits, and § 410.152 is amended to reflect adjustments to the supplier payment.

Indexing the Part B Deductible to Inflation

CMS will finalize changes to § 489.30 that would align regulatory text to the deductible and coinsurance changes introduced as part of the IRA through inflation adjustments and exceptions for insulin (when used via DME) from deductibles.

- **Request for Information (RFI): Drugs and Biologicals which are Not Usually Self-Administered by the Patient, and Complex Drug Administration Coding**

CMS did not finalize any changes because of the comments received. At this time, no changes will be made to how MACs determine their Self-Administered Drug lists. Instead, CMS indicated that further discussions and engagement may result in future rulemaking.

- **Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs to provide Refunds with Respect to Discarded Amounts (§§ 414.902 and 414.940) -** [February 28, 2025]

Provision of Information to Manufacturers

CMS finalized all of the following major steps they identified in the proposed rule:

1. provision of a preliminary report to manufacturers by December 31, 2023 with discarded amounts from first two quarters of CY2023.
2. Initial refund report will be sent on December 31, 2024 for CY2023. All subsequent reports will be sent to manufacturers by September 30.
3. All following refund reports will be sent one year from previous report, and will include 'new refund quarters', as well as 'updated refund quarters' to account for the delays in claims submission by providers and suppliers.
4. Define 'new refund quarters' as calendar quarters in the preceding coverage year, and 'updated refund quarters' from 2 years prior to the submission, which would include lagging claims which were not captured in preceding year's 'new refund quarters' in § 414.902.

Manufacturer Provision of Refund

CMS finalized revisions to § 414.940(b) and § 414.940(b)(2) to reflect the timelines for refunds to give manufacturers two months to submit refunds to CMS unless there is a dispute. Manufacturers must submit refunds within one month of dispute resolution. As such, upon receipt of the initial report on December 31, 2024, manufacturers must submit a refund by February 28, 2025. In subsequent years, upon receipt of the report on September 30, manufacturers must submit a refund by December 31 of that year. CMS has finalized the proposed rule with no changes.

Calculation of Refund Amounts for Updated Quarters

CMS finalized revision of § 414.940 by adding the method of calculating revisions to the refund amount owed for quarters in the coverage year that is two years prior to the report. The refund amounts will be calculated for the lagging claims and any refund already paid will be subtracted from this amount. CMS has finalized the proposed rule with no changes.

Calculation of Refund for a Drug when there are Multiple Manufacturers

CMS finalized their calculations for estimating the refund amount for drugs with multiple manufacturers to identify number of sale units by national drug codes-11

(NDC-11) that are associated with Part B claims (HCPCS). The sold units by NDC-11 will be determined based on ASP reports submitted to CMS. CMS will attribute the refund liability among manufacturers by identifying unique labeler codes associated with the NDC-11s, as long as the claims exceed a minimum threshold of applicable percentage of ten. CMS has finalized the proposed rule with no changes.

Increased Applicable Percentage for Drugs with Unique Circumstances

CMS finalized revisions to § 414.902 to add definition of "low volume dose" and § 414.940(d) to add the increased applicable percentage of 90 percent for drugs with a low volume dose contained within 0.1mL or less and 45 percent for a drug with a low volume dose contained within 0.11mL to 0.4mL. The increased applicable percentage of 26 is also finalized for an orphan drug that is utilized by less than 100 beneficiaries per coverage year for the 3 most recent coverage years. All changes in the proposed rule have been finalized.

Application process for increased applicable percentages

CMS finalized the process for increased applicable percentages by establishing a timeline where a manufacturer may submit an application by February 1 prior to the effective coverage year with an FDA acceptance letter for product review, an FDA approval letter by September 1. Applicants must also submit a written request for their drug to be considered for an increased applicable percentage based on unique circumstances, FDA label (for approved drugs), justification for consideration and identification of unique circumstances, justification for the target applicable percentage amount being requested.

CMS modified the process identified in the proposed rule to allow manufacturers to submit application to CMS prior to FDA approval.

Clarification for the Definition of Refundable Drug

CMS finalized the definition of refundable drug to exclude units furnished under Medicare Advantage. CMS also clarified that Medicare Advantage plans may use the JW and JZ modifiers, but JW modifiers will not be used in refund calculations by CMS.

**Background/Rationale**

- **Provisions from the Inflation Reduction Act Relating to Drugs and Biologicals Payable Under Part B**

Payment for Drugs under Medicare Part B During an Initial Period

The two primary group of comments advocated for 1) accounting for reduction in physician reimbursements by establishing a limit of WAC plus 3 percent during the initial phase, 2) reducing the reimbursement in initial phase to WAC, as WAC is typically higher than ASP. CMS acknowledged that although there may be some initial reduction in physician reimbursement, it would be temporary, and that any reduction may be counterbalanced by the increase in reimbursement for biosimilars which have same or lower ASP as their reference biologic. CMS also noted that WAC plus 3 percent is the ceiling, and that Medicare Administrative Contractors (MAC) may choose to have a lower reimbursement for biosimilars in the initial phase.

Temporary Increase in Medicare Part B Payment for Certain Biosimilar Agents

There were no pertinent comments advocating for CMS to change the definition. These regulatory changes are being made to align with the statutory requirements specified in the IRA.

Inflation-Adjusted Beneficiary Coinsurance and Medicare Payment for Medicare Part B Rebatable Drugs.

CMS is aligning regulation with statutory requirements specified in the IRA. Comments included questions about inflation adjustment exceptions for drugs with severe shortages and supply chain disruptions, as well as exclusion of Medicare Part C units in inflation adjustment calculations pursuant to the language in the statute. CMS noted that these concerns had been addressed elsewhere and were not in scope of this rule.

Limitations on Monthly Coinsurance and Adjustments to Supplier Payment Under Medicare Part B for Insulin Furnished Through Durable Medical Equipment

CMS is aligning regulation with statutory requirements specified in the IRA. Comments included questions about whether insulin products drawn in syringes for self-administration, inserted into cartridges for use with pumps and injected into total parenteral nutrition (TPN) were subject to these coinsurance maximums. CMS clarified

that this regulation is only pertaining to insulin used through DME, and excludes insulin used for self-administration and insulin used as part of TPN (which is billed as a prosthetic).

- **Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs to Provide Refunds with Respect to Discarded Amounts**

Provision of Information to Manufacturers

CMS delayed implementation of discarded amount refund program which was created by section 90004 of the Infrastructure Investment and Jobs Act to align it better with the provisions of the Inflation Reduction Act. Some comments suggested that CMS should limit "updated refund quarters" to only include claims from a single calendar quarter. CMS disagreed with this suggestion as providers and suppliers are allowed to submit claims up to one year after service date, and their respective MACs also need time to process the claims.

Calculation of Refund for a Drug when there are Multiple Manufacturers

Currently, part B claims do not always include NDC-11 and a crosswalk is often used to identify NDC-11 values associated with HCPCS. CMS identified the simplest way to attribute liability for refunds among manufacturers by identifying all NDC-11s for Part B drug use and distributing liability by percentage of sales between different manufacturers, labelers and repackagers. This approach is also being used for the inflation rebate liability calculations in Medicare Part B. Comments discouraged CMS from adopting this methodology as the statute specifically requires recovering refunds for drugs with the waste, and current methodology may disadvantage manufacturers with smaller vial sizes, which may not have been discarded to the same extent as larger vial sizes. CMS disagreed as it had identified only eleven instances with multiple manufacturers for a single source drug and found vial and product sizes to be largely consistent among manufacturers. CMS agreed to monitor this methodology and how it may affect manufacturers.

Increased Applicable Percentage for Drugs with Unique Circumstances

CMS conducted a town hall with stakeholders, as well as solicited and considered extensive feedback on unique circumstances which may warrant changes in applicable percentages. They agreed to increase the applicable percentage for very

low volume drugs because of minimum volumetric requirements for safe manufacturing, which exceed the dosing in the FDA label. CMS also identified orphan drugs with less than 100 beneficiaries per calendar year due to wide variation in utilization and challenges that poses on manufacturers from year to year.

Application process for increased applicable percentages

Several commenters asked CMS to afford flexibility with application process, especially for manufacturers who may know with certainty about their manufacturing and supply chain processes. CMS modified the proposed rule to accommodate this request but required that the manufacturer must have an FDA review letter prior to the application submission. A timeline was established, consistent with the new technology addon product (NTAP) assessment process that currently exists.

## H. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (section III.B.)

**Finalized Changes**

- **Section 4113 of the CAA, 2023**

CMS finalized as proposed to make conforming regulatory text changes based on the CAA to applicable RHC and FQHC regulations in 42 CFR part 405 subpart X. Specifically, CMS finalized to include language to delay in-person requirements for mental health visits furnished by RHCs and FQHCs through telecommunication technology under Medicare beginning January 1, 2025.

- **Direct Supervision via Use of Two-way Audio/Video Communications Technology**

CMS finalized as proposed to extend the definition of direct supervision to permit virtual presence in RHCs and FQHCs through December 31, 2024.

- **Section 4121 of the CAA, 2023** – January 1, 2024

CMS finalized as proposed to codify payment provisions for Marriage and Family Therapists (MFTs) and Mental Health Counselors (MHCs) under 42 CFR part 405, subpart X. RHC and FQHCs will be paid under the RHC AIR and FQHC PPS, respectively, when MFTs and MHCs furnish RHC and FQHC services defined in §§ 405.2411 and

405.2446. As eligible RHC and FQHC practitioners, MFTs and MHCs would follow the same policies and supervision requirements as a PA, NP, CNM, CP, and CSW.

CMS also finalized as proposed to allow addiction counselors that meet all of the applicable requirements of clinical supervised experience in mental health counseling, and that are licensed or certified as MHCs, clinical professional counselors, or professional counselors by the State in which the services are furnished) to enroll in Medicare as MHCs. To remain consistent with payment policies for professionals billing Medicare under the PFS, CMS finalized that the definitions established for MFTs and MHCs under the PFS would also apply for RHCs and FQHCs. CMS also finalized to clarify that when MFTs and MHCs provide the services described in HCPCS code G0323 in an RHC or FQHC, the RHC or FQHC can bill HCPCS code G0511. Finally, CMS finalized to make several confirming regulatory changes to applicable RHC and FQHC regulations in 42 CFR part 405, subpart X.

- **Updates to Supervision Requirements for Behavioral Health Services furnished at RHCs and FQHCs**

CMS finalized as proposed to change the required level of supervision for behavioral health services furnished "incident to" a physician or NPP's services at RHCs and FQHCs to allow general supervision, rather than direct supervision. Accordingly, CMS finalized to revise the regulations at §§ 405.2413 and 405.2415 to reflect that behavioral health services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided by auxiliary personnel incident to the services of a physician (or another practitioner).

- **General Care Management Services in RHCs and FQHCs –** January 1, 2024

CMS finalized as proposed to include the CPT codes associated with the suite of services that comprise RPM and RTM in the general care management HCPCS code G0511 when these services are furnished by RHCs and FQHCs. RHCs and FQHCs that furnish RPM and RTM services will be able to bill these services using HCPCS code G0511, either alone or with other payable services on an RHC or FQHC claim for dates of service on or after January 1, 2024.

- **Payment for Community Heath Integration (CHI) and Principal Illness Navigation (PIN) Services in RHCs and FQHC**

CMS finalized as proposed to allow separate payment for CHI and PIN services in RHCs and FQHCs under the general care management HCPCS code G0511. Both CHI and PIN involve a person-centered assessment to better understand a patient's needs. CHI addresses unmet SDOH needs that affect the diagnosis and treatment of the patient's medical problems (e.g., facilitating access to community-based services, building self-advocacy skills). Principal Illness Navigation helps individuals who are diagnosed with high-risk conditions (for example, mental health conditions, substance use disorder, and cancer) identify and connect with appropriate clinical and support resources.

CMS also clarified that RHCs and FQHCs may bill HCPCS code G0511 multiple times in a calendar month, as long as all of the requirements for each service are met. They also noted that the placeholder HCPCS codes GXXX1 through GXXX4 that describe CHI and PIN services are replaced with HCPCS codes G0019, G0022, G0023, and G0024 respectively.

- **Proposed Revision to the Calculation of the Payment Amount for the General Care Management HCPCS Code G0511**

CMS finalized as proposed to revise the method of calculating HCPCS code G0511 so that payment for general care management is more appropriate, given the expansion of billable services under the code to include RPM, RTM, CHI, and PIN.

Specifically, CMS will take the weighted average of the base code and add-on code pairs, in addition to the individual base codes for all of the services that comprise HCPCS code G0511 by using the CY 2021 PFS utilization to calculate the payment rate for the general care management services furnished in RHCs and FQHCs on or after January 1, 2024. To calculate the weighted average, CMS multiplies the non-facility payment rate times the non-facility utilization for each code, sums the total, and then divides by the summed non-facility utilization for the codes included in the average.

- **Chronic Care Management (CCM) Services and Virtual Communication Services Requirement for Obtaining Beneficiary Consent**

CMS finalized as proposed to clarify when, how and by whom beneficiary consent for CCM services can be obtained. Specifically, informed consent to receive CCM

services must be obtained prior to the start of CCM services. Consent does not have to be obtained at the required initiating visit for CCM that must be performed by the RHC or FQHC practitioner, but it can be obtained at that time. Since the RHC or FQHC practitioner discusses CCM with the beneficiary during the initiating visit, if consent is separately obtained, it may be obtained under general supervision, and can be verbal as long as it is documented in the medical record and includes notification of the required information. That is, beneficiary consent can be obtained at the same time that the CCM service is initiated by auxiliary staff who work to furnish the CCM services. Further, there need not be an employment relationship between the person obtaining the consent and the RHC or FQHC practitioner. That is, the clinical staff obtaining the verbal or written consent can be under contract with the RHC or FQHC. CMS also will require the beneficiary be informed on the availability of CCM services; that only one practitioner can furnish and be paid for these services during a calendar month; and of the right to stop the CCM services at any time.

Regarding virtual communication, CMS finalized as proposed to clarify that the consent from the beneficiary to receive virtual communication services can be documented by auxiliary staff under general supervision, as well as by the billing practitioner.

**Background/Rationale**

- **Implementation of the CAA, 2023**

Many commenters supported the extension of telehealth flexibilities for RHCs and FQHCs and the delay of the in-person requirements for mental health services. Several commenters also requested the COVID-19 flexibilities be made permanent; however, CMS noted it does not have the authority to make these flexibilities permanent. Other commenters urged CMS to revise the “medical visit” definition so that these services can be furnished via telecommunication technologies similar to what was finalized in the CY 2022 PFS final rule. CMS noted that this request is out of scope since it did not make proposals in this rulemaking related to the definition of medical visit. However, they anticipate the telehealth extension would mitigate gaps in care concerns.

One commenter encouraged CMS not to impose requirements for in-person services beyond what is statutorily required, noting that it can pose a barrier for individuals seeking mental health treatment. CMS notes that there are exceptions to the in-person visit requirement that can be used, per § 405.2463(b)(3).

- **Direct Supervision via Use of Two-way Audio/Video Communications Technology**

All commenters supported extending the definition of direct supervision to permit virtual presence beyond December 31, 2024. Commenters noted that they believe direct supervision has become increasingly challenging and the option to provide virtual direct supervision has enhanced the quality and provision of healthcare services beneficiaries have received in medically underserved, rural communities. They also noted using audio-visual technology for supervision during the COVID-19 PHE did not create significant clinical safety concerns and subsequent formal assessments will confirm the safety of virtual direct supervision. Virtual direct supervision facilitates timely access to services that on-site personnel could effectively deliver.

- **Section 4121 of the CAA, 2023**

Commenters supported the proposals related to MFTs and MHCs, noting that these changes will enable health centers to maximize their workforce to meet their patients' needs. One commenter suggested that CMS use the definition of MHC that would include all appropriately trained and qualified health professionals currently licensed by States or recognized by the National Health Services Corps (NHSC). CMS agreed and clarified that mental health practitioners who meet all of the applicable statutory qualifications for the mental health counselor benefit category but are licensed by their State under a different title, are eligible to enroll in Medicare under the Part B "Mental Health Counselor" statutory benefit category.

- **Updates to Supervision Requirements for Behavioral Health Services furnished at RHCs and FQHCs**

Commenters were overwhelmingly supportive of the proposal to change the required level of supervision for behavioral health services furnished in RHCs and

FQHCs "incident to" a physician or NPP's services to general supervision rather than direct supervision.

- **General Care Management Services in RHCs and FQHCs**

All commenters expressed support for the proposal to allow RHCs and FQHCs to bill separately for RPM and RTM services. Some commenters stated that adding RPM and RTM services to the general care management code is not sustainable or equitable and would like CMS to create a separate code(s) for RPM and RTM services that can be billed outside of the RHC AIR or FQHC PPS. CMS noted that they believe a separate payment for these services along with revised methodology for calculating the rate will provide adequate payment and support access to these services; however, they will continue to monitor and explore other options.

- **Payment for Community Heath Integration (CHI) and Principal Illness Navigation (PIN) Services in RHCs and FQHC**

Commenters recommended that CMS consider a standalone HCPCS code for CHI and PIN services in RHCs and FQHCs because of the potential for increased claim denials for duplicate billing when numerous care management services are included in HCPCS code G0511 that would potentially require RHCs and FQHCs to bill for more than one care management service on the same day for the same beneficiary or duplicate claims denied when multiple care management services are filed on successive days for the same beneficiary. CMS noted that providers may bill HCPCS code G0511 multiple times in a calendar month as long as all requirements are met and there is not double counting. CMS believes allowing a separate payment for these services along with their revised methodology for calculating the rate for HCPCS code G0511 will provide adequate payment and support access to these services.

Commenters supported CMS' proposal to reimburse for an SDOH Risk Assessment as part of the Annual Wellness Visit (AWV). Many commenters requested clarification on the payment mechanics for the SDOH Risk Assessment as an additional element of the AWV in relation to the FQHC and RHC bundled payment mechanisms. CMS noted that this is out of scope for this rule, though they will take it into consideration in future rulemaking.

- **Proposed Revision to the Calculation of the Payment Amount for the General Care Management HCPCS Code G0511**

A few commenters expressed concerns that, since the code can only be billed once per calendar month, the increased payment rate may not sufficiently account for the resources required to provide chronic care management, CHI and/or PIN, as well as remote monitoring when several of these services are provided in the same month. CMS appreciated these concerns; but noted that RHCs and FQHCs may bill HCPCS code G0511 multiple times in a calendar month, as long as all of the requirements are met, and resource costs are not counted more than once.

- **Chronic Care Management (CCM) Services and Virtual Communication Services Requirement for Obtaining Beneficiary Consent**

CMS reiterated the importance of obtaining advance beneficiary consent to receive CCM services was to ensure the beneficiary is informed, educated about CCM services, and is aware of applicable cost sharing. In addition, querying the beneficiary about whether another practitioner is already providing CCM services helps to reduce the potential for duplicate provision or billing of the services. CMS believes the same philosophy applies to consent for virtual communications as it does for CCM.

## I. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) Conditions for Certification or Coverage (CfCs) (section III.C.)

**Finalized Changes**

- **Definitions**

CMS finalized adding conforming changes to the CfCs to include MFT and MHC services to indicate that RHC and FQHCs can offer these services under their Medicare certification. At § 491.2, Definitions, CMS proposes adding a definition of MFTs and MHCs by cross-referencing the definitions proposed at §§ 410.53 and 410.54. CMS also proposes to add CP, CSW, and CNM professionals to § 491.2, Definitions, and cross-reference the definitions established in the payment requirements at § 410.77(a), §410.71(d), §410.73(a) respectively.

CMS finalized with modification of its revision of the existing "nurse practitioner" (NP) definition at § 491.2(1). CMS removed the proposed language specifying that an NP be certified in primary care. CMS however still did finalize requiring the nurse practitioner be certified by a recognized certifying body and possess a master's or doctoral degree in nursing.

- **Staffing and Staff Responsibilities**

At § 491.8(a)(3), CMS finalized as proposed to add MFT and MHC to the list of staffing and staff responsibilities, allowing them to be the owner, employee, or furnish services under contract to the clinic or center. CMS also finalized as proposed adding MFTs and MHCs to the list of other practitioners who can provide services when the clinic or center is open and operating. CMS also finalized to update § 491.8(a)(6) to include MFTs and MHCs to the list of other practitioners who are eligible to furnish services and who can provide services, within the scope of practice, when the clinic or center is open and operating.

**Background/Rationale**

- **Definitions**

Commenters supported the proposed revision of the NP definition at § 491.2 to remove naming specific certifying boards for NPs and adding education requirements. However, commenters recommend removing the primary care certification specification to allow health centers to employ the most qualified candidates who could best serve the clinic or center's patient populations. CMS agreed, noting that eliminating the need for primary care certification for NPs could aid in resolving staffing shortages that healthcare facilities are experiencing in underserved and rural communities.

- **Staffing and Staff Responsibilities**

Many commenters supported expanding Medicare coverage to include MFT and MHC services in RHCs and FQHCs. Commenters expressed their appreciation for the discussion of the specific barriers to accessing mental health and substance use disorder services for people living in rural areas and areas where there are shortages of healthcare professionals.

## J. Medicare Shared Saving Program (section III.G.)

**Finalized Changes**

- **Revise Quality Reporting and Quality Performance Requirements**

CMS is finalizing its proposal to allow Shared Savings Program ACOs the option to report quality measures, including the CAHPS for MIPS survey, under the Alternative Payment Model Performance Pathway (APP) on only their Medicare beneficiaries through Medicare Clinical Quality Measures (CQMs).

CMS is finalizing its proposal to amend the definition of "Collection Type" in section IV.A.4.f.(1)(b) of this proposed rule to include the Medicare CQM as an available collection type in MIPS for ACOs that participate in the Shared Savings Program. Additionally, CMS proposes to establish data submission and completeness criteria pertaining to the Medicare CQMs for the MIPS quality performance category.

CMS is finalizing the proposal to define a beneficiary eligible for Medicare CQM at § 425.20 as a beneficiary identified for purposes of reporting Medicare CQMs for ACOs participating in the Medicare Shared Savings Program (Medicare CQMs) who is either of the following:

- A Medicare fee-for-service beneficiary who meets the criteria for a beneficiary to be assigned to an ACO described at § 425.401(a); and
- Had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a PA, NP, or CNS.
- A Medicare fee-for-service beneficiary who is assigned to an ACO in accordance with § 425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

CMS is finalizing its proposal to establish the data completeness criteria threshold for the Medicare CQM collection type, in which a Shared Savings Program ACO that meets the reporting requirements under the APP would submit quality measure data for Medicare CQMs on the APM Entity's applicable beneficiaries eligible for the Medicare CQM, as proposed at § 425.20, who meet the measure's denominator criteria.

Specifically, CMS is finalizing the proposal data completeness criteria thresholds for Medicare CQMs:

- At least 75 percent for the CY 2024, CY 2025, and CY 2026 performance periods; and 2026, 2027, and 2028 MIPS payment years.

CMS is finalizing its proposal to add three measures as Medicare CQMs to the APP measure set for Shared Savings Program ACOs beginning with performance year 2024 and subsequent performance years. ACOs may report the 3 Medicare CQMs, or a combination of eCQMs/MIPS CQMs/Medicare CQMs, to meet the Shared Savings Program quality reporting requirement at § 425.510(b) and the quality performance standard at § 425.512(a)(5). The three measures are:

- Quality ID#: 001 Diabetes: Hemoglobin A1c (HbA1c) Poor Control;
- Quality ID#: 134 Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and
- Quality ID#: 236 Controlling High Blood Pressure

CMS is finalizing the proposal that for the first performance year of an ACO's first agreement period under the Shared Savings Program, if the ACO reports data via the APP and meets MIPS data completeness requirement at § 414.1340 and receives a MIPS Quality performance category score under § 414.1380(b)(1), the ACO will meet the quality performance standard under the Shared Savings Program, if:

- For performance year 2024. The ACO does report the 10 CMS Web Interface measures or the 3 eCQMs/MIPS CQMs/Medicare CQMs, and administers a CAHPS for MIPS survey under the APP.
- For performance year 2025 and subsequent performance years. The ACO reports the 3 eCQMs/MIPS CQMs/Medicare CQMs and does administer a CAHPS for MIPS survey under the APP.

Additionally, CMS is finalizing the proposing that an ACO would not meet the quality performance standard or the alternative quality performance standard if:

- For performance year 2024, if an ACO
    - does not report any of the 10 CMS Web Interface measures or any of the three eCQMs/MIPS CQMs/Medicare CQMs and
    - does not administer a CAHPS for MIPS survey under the APP.

- For performance year 2025 and subsequent performance years, if an ACO
    - does not report any of the three eCQMs/MIPS CQMs/Medicare CQMs and
    - does not administer a CAHPS for MIPS survey under the APP.

CMS is finalizing the proposal that new benchmarks for scoring ACOs on the Medicare CQMs under MIPS would be developed in alignment with MIPS benchmarking policies. Specifically, CMS is finalizing its proposal for performance year 2024 and 2025 to score Medicare CQMs using performance period benchmarks. For PY 2026 and subsequent years, CMS is finalizing the proposal to transition using historical benchmarks for Medicare CQMs when baseline period data are available to establish historical benchmarks in a manner that is consistent with the MIPS benchmarking policies at § 414.1380(b)(1)(ii).

- **Expanding the Health Equity Adjustment to Medicare CQMs**

CMS is finalizing the proposal that ACOs that report Medicare CQMs would be eligible for the health equity adjustment to their quality performance category score when calculating shared savings payments. Specifically, CMS will revise § 425.512(b) to specify that, for PY 2024 and subsequent PYs, they would calculate a health equity adjusted quality performance score for an ACO that reports the three Medicare CQMs or a combination of eCQMs/MIPS CQMs/Medicare CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 for each measure, and administers the CAHPS for MIPS survey.

CMS is also finalizing the proposal to revise the underserved multiplier calculation to specify the calculations in more detail and bring greater consistency between the calculation of the proportion of ACOs' assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85 and the proportion of ACOs' assigned beneficiaries who are enrolled in Medicare Part D LIS or are dually eligible for Medicare and Medicaid.

CMS is finalizing the proposal to remove beneficiaries who do not have a numeric national percentile rank available for ADI from the health equity adjustment calculation for performance year 2023 and subsequent performance years. Beneficiaries without a national percentile ADI rank would appear neither in the numerator nor in the denominator of the proportion.

CMS is finalizing the proposal to modify the calculation of the proportion of assigned beneficiaries dually eligible for Medicare and Medicaid and the calculation of the proportion of assigned beneficiaries enrolled in LIS to use the number of beneficiaries rather than person years for calculating the proportion of the ACO's assigned beneficiaries who are enrolled in LIS or who are dually eligible for Medicare and Medicaid starting in performance year 2024.

For performance year 2024 and subsequent performance years, CMS is finalizing the proposal to use historical submission-level MIPS Quality performance category scores to calculate the 40th percentile MIPS Quality performance category score. CMS proposes to use a rolling 3-performance year average with a lag of 1-performance year. CMS proposes that for PY 2024 and subsequent performance years, if:

1. an ACO reports all required measures under the APP and meets the data completeness requirement at § 414.1340 for all required measures and receives a MIPS Quality performance category score under § 414.1380(b)(1), and
2. the ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score for the performance year is reduced due to measure exclusion under § 414.1380(b)(1)(vii)(A),

CMS would use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, to determine whether the ACO meets the quality performance standard required to share in savings at the maximum rate under its track for the relevant performance year.

CMS is finalizing the proposal to revise § 425.512(b)(3)(ii)(B) to state that CMS assigns a value of 0 for each measure that CMS does not evaluate because the measure is unscored. These changes would be effective for performance year 2023 and subsequent performance years.

CMS is finalizing the proposal that quality measures impacted by the MIPS policy at § 414.1380(b)(1)(vii)(A) are unscored measures for the purposes of calculating the health equity adjustment; therefore, excluded measures would not render an ACO ineligible for the health equity adjustment as long as the ACO reports all required

measures under the APP and meets the data completeness requirement at § 414.1340 for all required measures and receives a MIPS Quality performance category score.

CMS is finalizing a proposal to change the MIPS policy to remove the 10 percent threshold for changes to codes, clinical guidelines, or measure specifications for all measure types.

- **Alignment of CEHRT Requirements for Shared Savings Program ACOs with MIPS -** [Performance Year 2025]

CMS is finalizing the proposal to require Spanish language administration of the CAHPS for MIPS survey for MIPS eligible clinicians reporting MIPS. Specifically, they propose to require MIPS eligible clinicians to contract with a CMS-approved survey vendor that, in addition to administering the survey in English, will administer the Spanish survey translation to Spanish-preferring patients using the procedures detailed in the CAHPS for MIPS Quality Assurance Guidelines beginning with 2025 survey administration.

CMS is finalizing the proposal to sunset the Shared Savings Program CEHRT threshold requirements and modify regulations at § 425.506(f) to indicate they will be applicable only through PY 2024. Further, CMS proposes, for PYs beginning on or after January 1, 2025, to require that all MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) participating in the ACO, regardless of track, satisfy all the following:

- Report the MIPS Promoting Interoperability (PI) performance category measures and requirements to MIPS as either of the following;
    - All MIPS eligible clinicians, QPs, and partial QPs participating in the ACO as an individual, group, or virtual group; or
    - The ACO as an APM entity.
- Earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level. A MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity may be excluded from the requirements proposed at § 425.507(a) if the MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity:
    - Does not exceed the low volume threshold set forth at § 414.1310(b)(1)(iii);

    - Is an eligible clinician as defined at § 414.1305 who is not a MIPS eligible clinician and has opted to voluntarily report measures and activities for MIPS.
    - Has not earned a performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level.
- A MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity may be excluded from the requirements proposed at § 425.507(a) if the MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity:
    - Does not exceed the low volume threshold;
    - Is an eligible clinician as defined at § 414.1305 who is not a MIPS eligible clinician and has opted to voluntarily report measures and activities for MIPS; or
    - Has not earned a performance category score for the MIPS Promoting Interoperability performance category because the MIPS Promoting Interoperability performance category has been reweighted.

- **Updating Public Reporting Requirements -** [Performance Year 2025]

CMS is finalizing the proposal that MIPS eligible clinicians, QPs, and Partial QPs who would be excluded from reporting under the proposed regulation at § 425.507(b) may be excluded from the number of MIPS eligible clinicians, QPs, or Partial QPs that the ACO publicly reports under proposed regulation at § 425.308(b)(9). However, if such MIPS eligible clinicians, QPs, and Partial QPs do report the MIPS PI performance category as an individual, group, or virtual group or the ACO reports the MIPS PI performance category as an APM entity, the MIPS eligible clinicians, QPs, and Partial QPs should be included in the number of MIPS eligible clinicians, QPs, and Partial QPs that the ACO publicly reports.

- **Updating Annual Certification Requirements -** [Performance Year 2025]

CMS is finalizing the proposal to sunset the CEHRT certification requirement in the Shared Savings Program by amending regulations to no longer require ACO clinicians to report the percentage of eligible clinicians participating in the ACO that use CEHRT

to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage specified at § 425.506(f).

- **Revise the Policies for Determining Beneficiary Assignment**

CMS is finalizing a proposal to include health status information such as risk profile and chronic condition subgroups to the extent that such data would aid ACOs in identifying patients that meet the denominator criteria for the Medicare CQM Specifications. CMS would also provide technical assistance to ACOs when reporting the Medicare CQMs, including providing technical resource documents.

- **Revise the Requirement to Meet the Case Minimum Requirement for Quality**

CMS is finalizing the proposal to replace the references to meeting the case minimum requirement at § 414.1380 with the requirement that the ACO must receive a MIPS Quality performance category score under § 414.1380(b)(1) to meet the quality performance standard.

- **Determining Beneficiary Assignment Under the Shared Savings Program -** [Performance Year 2025]

CMS is finalizing the proposal to use an expanded window for assignment in a new step three to the claims-based assignment process to identify additional beneficiaries for ACO assignment. CMS is also proposing to modify the definition of "assignable beneficiary" to be consistent with the use of an expanded window for assignment to identify additional beneficiaries to include in the assignable population after application of the existing methodology.

CMS is finalizing the proposal to add a new definition of "Expanded window for assignment" in § 425.20 to mean the 24-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both that includes the applicable 12-month assignment window and the preceding 12 months.

CMS is finalizing the proposal to add a new step three to the beneficiary assignment methodology that would occur after the current steps one and two and would apply only to beneficiaries who do not meet the pre-step requirement but who received at least one primary care service during the proposed expanded window for assignment

with an ACO professional who is a primary care physician or a physician who has one of the specialty designations included in § 425.402(c).

- Beneficiaries qualifying for step three would be assigned based on the plurality of allowed charges for primary care services during this expanded window for assignment.
- Second, the proposed revision to the definition of an assignable beneficiary would similarly include beneficiaries who receive at least one primary care service during the proposed expanded window for assignment from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c).
- In combination with using the expanded window for assignment for identifying beneficiaries who received at least one primary care service from a primary care physician or a physician whose specialty designation is used in assignment, under both the proposed step three for assignment and proposed revised definition of an assignable beneficiary, CMS would continue to consider whether beneficiaries received at least one primary care service during the 12-month assignment window.
- CMS proposes that these changes would be effective for the performance year beginning on January 1, 2025, and subsequent performance years.

CMS is also finalizing the proposal to modify the regulations at § 425.400(c)(2)(i) and (ii) to incorporate references to the expanded window for assignment, such that CMS would apply the additional primary care service codes to all months of the assignment window or applicable expanded window for assignment when the assignment window or applicable expanded window for assignment includes any month(s) during the COVID-19 PHE.

- **Revise the Definition of an Assignable Beneficiary -** [Performance Year 2025]

CMS is finalizing the proposal that a Medicare fee-for-service beneficiary who does not meet assignment requirements but who meets both of the following criteria would also be considered an assignable beneficiary:

- Receives at least one primary care service with a date of service during a specified 24-month expanded window for assignment from a Medicare-

enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c).

- Receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled practitioner who is a nurse practitioner, physician assistant, or a clinical nurse specialist.

CMS is also finalizing the proposal to specify that the assignable population would be identified for the relevant benchmark year, or the performance year (as applicable) using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii):

- In §§ 425.652(a)(5)(v)(A) and (b)(2)(iv)(A), provisions on calculating the county-level share of assignable beneficiaries who are assigned to the ACO for each county in the ACO's regional service area for purposes of calculating the blended national-regional growth rates used in trending and updating the benchmark.
- In the provision on redetermination of the regional adjustment for the second or each subsequent performance year during the term of the agreement period in § 425.652(a)(9)(ii).
- In the provision on the calculation of average county FFS expenditures for assignable beneficiaries in each county in the ACO's regional service area in § 425.654(a)(1)(i).
- In the provision on adjusting for differences in severity and case mix between the ACO's assigned beneficiary population for BY3 and the assignable beneficiary population for the ACO's regional service area for BY3, in calculating average per capita expenditures for the ACO's regional service area, in § 425.656(b)(3).

CMS is also finalizing the proposal to specify in the proposed new provision at § 425.655(b)(1) that the assignable population that would be used to calculate average county prospective HCC and demographic risk scores for purposes of calculating the proposed regional risk score growth cap adjustment factor would be identified for the relevant benchmark year or the performance year (as applicable) using the assignment window or expanded window for assignment that is consistent with the

beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

- **Revise the Definition of Primary Care Services used in Shared Savings**

CMS is finalizing as proposed the revisions to the definition of primary care services used for assignment in the Shared Savings Program regulations to include the following additions:

1. Smoking and Tobacco-use Cessation Counseling Services CPT codes 99406 and 99407;
2. Remote Physiologic Monitoring CPT codes 99457 and 99458;
3. Cervical or Vaginal Cancer Screening HCPCS code G0101;
4. Office-Based Opioid Use Disorder Services HCPCS codes G2086, G2087, and G2088;
5. Complex Evaluation and Management Services Add-on HCPCS code G2211, if finalized under Medicare FFS payment policy;
6. Community Health Integration services HCPCS codes GXXX1 and GXXX2, if finalized under Medicare FFS payment policy;
7. Principal Illness Navigation (PIN) services HCPCS codes GXXX3 and GXXX4, if finalized under Medicare FFS payment policy;
8. SDOH Risk Assessment HCPCS code GXXX5, if finalized under Medicare FFS payment policy;
9. Caregiver Behavior Management Training CPT Codes 96202 and 96203, if finalized under Medicare FFS payment policy; and
10. Caregiver Training Services CPT codes 9X015, 9X016, and 9X017

CMS is also finalizing the proposal to specify a revised definition of primary care services in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(viii) to include the list of HCPCS and CPT codes specified which would be applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2024, and subsequent performance years The proposed additional CPT codes:

1. 99406 and 99407; and
2. 99457 and 99458; and

3. 96202 and 96203

- **Revise the Policies on the Shared Savings Program's Benchmarking Methodology**

CMS is finalizing the proposal to revise the Shared Savings Program regulations governing the calculation of the regional growth rate when updating the historical benchmark between Benchmark Year (BY) 3 and the performance year at § 425.652(c) to incorporate a regional risk score growth cap adjustment factor.

CMS is also finalizing the proposal to calculate and apply the regional adjustment in combination with the prior savings adjustment, if applicable, for ACOs in agreement periods starting on January 1, 2024, and in subsequent years:

- CMS would continue to calculate the original uncapped regional adjustment by Medicare enrollment type using the applicable percentage phase-in weight based on whether the ACO has lower or higher spending compared to its regional service area and the ACO's agreement period subject to a regional adjustment as described in § 425.656(d).
- CMS would continue to apply the 5 percent cap on positive regional adjustments and the -1.5 percent cap and offset factor on negative regional adjustments at the enrollment type level, as finalized in the CY 2023 PFS final rule and described in § 425.656(c). For the performance year beginning on January 1, 2025, and subsequent performance years, the national assignable fee-for-service population used to calculate the caps would reflect the revised definition of assignable beneficiary that incorporates the expanded window for assignment as proposed in section III.G.3.a of this proposed rule.
- After applying the cap and offset factor (if applicable), CMS would express the regional adjustment as a single per capita value by calculating a person year weighted average of the Medicare enrollment type-specific regional adjustment values.
- If the ACO's regional adjustment amount (expressed as a single per capita value) is positive, the ACO would receive a regional adjustment, according to the approach we finalized in the CY 2023 PFS final rule. CMS would apply the

enrollment type-specific regional adjustment amounts separately to the historical benchmark expenditures for each Medicare enrollment type.

- If the ACO is also eligible for a prior savings adjustment, the ACO would receive the higher of the two adjustments.
- If the regional adjustment amount (expressed as a single per capita value) is higher, CMS would apply the enrollment type-specific regional adjustment amounts separately to the historical benchmark expenditures for each Medicare enrollment type.
- If the prior savings adjustment is higher, CMS would apply the adjustment in the manner finalized in the CY 2023 PFS final rule as a flat dollar amount applied separately to the historical benchmark expenditures for each Medicare enrollment type.

- If the ACO's regional adjustment amount (expressed as a single per capita value) is negative, the ACO would receive no regional adjustment to its benchmark for any enrollment type.
  - If the ACO is eligible for a prior savings adjustment, it would receive the prior savings adjustment as its final adjustment, without any offsetting reduction for the negative regional adjustment.

CMS is finalizing the proposal describe how CMS would determine and apply the adjustment to an ACO's benchmark depending on whether the ACO is eligible for a prior savings adjustment and whether the ACO's regional adjustment, expressed as a single value, is positive or negative. This provision would also establish that if an ACO is not eligible to receive a prior savings adjustment and has a regional adjustment, expressed as a single value that is negative or zero, the ACO will not receive an adjustment to its benchmark.

CMS is finalizing the proposal to revise § 425.656 (which describes the calculation of the regional adjustment) and § 425.658 (which describes the calculation of the prior savings adjustment) to include certain elements of each calculation that were previously described in § 425.652(a)(8). Specifically, CMSs propose to revise § 425.656 to redesignate paragraphs (d) and (e) as paragraphs (e) and (f) (respectively) and to specify in a new paragraph (d) that we would express the regional adjustment as a single value, and use this value in determining whether a regional adjustment or a

prior savings adjustment would be applied to the ACO's benchmark in accordance with § 425.652(a)(8) (as revised under this proposed rule).

CMS is finalizing the proposal to add a new paragraph (c) under § 425.658 specifying that CMS would calculate the per capita savings adjustment as the lesser of 50 percent of the pro-rated average per capita savings amount and the cap equal to 5 percent of national per capita FFS expenditures for assignable beneficiaries for BY3 expressed as a single value by taking a person-year weighted average of the Medicare enrollment-type specific values.

CMS is finalizing the proposal to modify the calculation of the regional update factor used to update the historical benchmark between benchmark year (BY) 3 and the performance year by capping an ACO's regional service area risk score growth through use of an adjustment factor to provide more equitable treatment for ACOs and for symmetry with the cap on ACO risk score growth.

CMS is finalizing the proposal to specify the circumstances in which CMS would recalculate the prior savings adjustment for changes in values used in benchmark calculations due to compliance action taken to address avoidance of at-risk beneficiaries, or as a result of the issuance of a revised initial determination of financial performance for a previous performance year.

CMS is finalizing the proposal to specify use of the CMS-HCC risk adjustment methodology applicable to the calendar year corresponding to the performance year in calculating prospective HCC risk scores for Medicare FFS beneficiaries for the performance year, and for each benchmark year of the ACO's agreement period.

- **Modify Prior Savings Adjustment**

CMS is finalizing the proposal to modify the list of circumstances for adjusting an ACO's historical benchmark in § 425.652(a)(9) to include two additional scenarios:

1. A change in savings earned by an ACO in a benchmark year in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries, or
2. A change in the amount of savings or losses for a benchmark year due to a reopening of a prior determination of ACO shared savings or shared losses and the issuance of a revised initial determination under § 425.315

CMS is finalizing the proposal to adjust benchmark due to the two conditions being considered to be used in financial reconciliation for a performance year, any determination that changes the amount of the ACO's savings or losses in any of the benchmark years under §§ 425.315 or 425.316(b)(2)(ii)(B) or (C) must be issued no later than the date of the initial determination of shared savings or shared losses through financial reconciliation for the relevant performance year under § 425.605(e) or § 425.610(h).

CMS is also finalizing the proposal to consider whether this prior ACO is impacted by the following when determining whether to issue an adjusted benchmark:

1. A change in the amount of savings calculated for any of the ACO's benchmark years eligible for inclusion in the prior savings adjustment in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries; or
2. A revised initial determination issued under § 425.315 impacts the determination of the ACO's savings or losses for one of the benchmark years.

- **Refine How Benchmark Years are Risk Adjusted**

CMS is finalizing the proposal to codify paragraph (b) of § 425.659 their approach to determining Medicare FFS beneficiary prospective HCC risk scores for Shared Savings Program benchmark and performance year calculations. Specifically, CMS is finalizing codification of:

- The current practice of calculating risk scores for Medicare FFS beneficiaries for a performance year, which provides that CMS uses the CMS-HCC risk adjustment methodology applicable for the corresponding calendar year.
- The current practice for agreement periods beginning before January 1, 2024, of applying the CMS-HCC risk adjustment methodology for the calendar year corresponding to benchmark year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year of the agreement period.
- For agreement periods beginning on January 1, 2024, and in subsequent years, CMS would apply the CMS-HCC risk adjustment methodology for the calendar year corresponding to the performance year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year of the agreement period.

CMS is finalizing the proposal at § 425.659(b)(2) to codify current practices for calculating prospective HCC risk scores for a benchmark or performance year. Specifically, CMS will:

- Remove the MA coding intensity adjustment, if applicable.
- Renormalize prospective HCC risk scores by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) based on a national assignable FFS population for the relevant benchmark or performance year.
- Calculate the average prospective HCC risk score by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) to risk adjust benchmark calculations also performed by Medicare enrollment type.

CMS is finalizing the proposal to adjust the benchmark to account for CMS-HCC risk adjustment model changes during the term of the agreement period to maintain uniformity between the calculation of prospective HCC risk scores for the performance year and each benchmark year.

CMS is also finalizing the proposal to revise the list of circumstances for adjusting the historical benchmark for the second and each subsequent performance year during the term of the agreement period at § 425.652(a)(9) to include a change in the CMS-HCC risk adjustment methodology used to calculate prospective HCC risk scores.

- **Modify AIP Eligibility Requirements to Allow ACOs to Advance to Performance-Based Risk During the 5-Year Agreement Period**

CMS is finalizing the proposal to modify Advance Investment Payments (AIP) eligibility requirements to allow an ACO receiving advance investment payments to transition to two-sided risk within its 5-year agreement period under the BASIC track's glide path. Specifically, CMS proposes to modify § 425.630(b)(2) and (3) to allow an eligible ACO receiving advance investment payments to advance to performance-based risk beginning in PY3 of the ACO's agreement period.

CMS is also finalizing the proposes to modify § 425.316(e)(2) to specify that CMS would cease payment of advance investment payments if CMS determines that an ACO

approved for AIP became experienced with performance-based risk Medicare ACO initiatives during the first or second performance year of its agreement period or became a high revenue ACO during any performance year of the agreement period in which it received advance investment payments.

- CMS also is finalizing the proposal to modify § 425.316(e)(2)(i) to specify that CMS will cease payment of advance investment payments no later than the quarter after the ACO became experienced with performance-based risk Medicare ACO initiatives or became a high revenue ACO.
    - Under this proposal, an ACO could not use advance investment payments to fund repayment mechanisms or repay shared losses. This limitation also reduces the risk that ACOs stretch themselves beyond their financial capacity while receiving advance investment payments by taking on large amounts of risk.

CMS is finalizing the proposal to Modify ACO reporting requirements to require ACOs to submit spending plan updates to CMS in addition to publicly reporting spend plan updates.

- **Modify AIP Recoupment and Recovery Policies for Early Renewing ACOs**

CMS is finalizing the proposal to amend § 425.630(g)(4) to create a limited exception to the policy of recovering advance investment payments from an ACO that voluntarily terminates its participation agreement for the agreement period during which it received advance investment payments. Under this proposal, CMS would not seek to collect all advance investment payments received from an ACO, if the ACO voluntarily terminates its participation agreement at the end of PY2 or later during the agreement period in which it received advance investment payments, provided that the ACO immediately enters into a new participation agreement with CMS under any level of the BASIC track's glide path or the ENHANCED track. Instead, CMS would carry forward any remaining balance of advance investment payments owed by the early renewing ACO into the ACO's new agreement period.

CMS is also finalizing the proposal to allow an ACO approved for AIP to early renew its participation agreement before the expiration of its current agreement if the ACO terminates its current participation agreement effective on or after December 31 of the

ACO's second performance year. By requiring the ACO to maintain its current agreement period for the first two years, the ACO will receive all its advance investment payments prior to renewing its participation agreement.

CMS is finalizing the proposal that in such circumstances, the early renewing ACO must continue to repay the advance investment payments through shared savings earned in the subsequent agreement period. If an ACO early renews prior to PY3, it will no longer comply with the eligibility requirements for receiving payments and may be subject to compliance actions under §§ 425.216 and 425.218. An ACO may spend an advance investment payment over its entire agreement period.

CMS is finalizing the proposal to amend § 425.630(e)(3) to permit an early renewing ACO to spend advance investment payments in its second agreement period so long as the advance investment payments are spent within 5 performance years of when it began to receive advance investment payments. If the ACO does not spend all the advance investment payments received by the end of the fifth performance year, the ACO must repay any unspent funds to CMS.

CMS is also finalizing the proposal to permit CMS to terminate advance investment payments for future quarters to an ACO that has provided CMS with notice of termination in accordance with § 425.220(a) if the ACO will not immediately enter a new agreement period. This avoids distributing advance investment payments to an ACO from which CMS would subsequently need to recover such payments. If finalized, these proposed changes would be effective January 1, 2024.

- **Permit Reconsideration Review of Quarterly Payment Calculations**

CMS is finalizing the proposal to permit an ACO to request a reconsideration review for all advance investment payment quarterly payment calculations, not just instances where no payments were distributed.

CMS is also finalizing the proposal to revise § 425.630(f) to provide that CMS would notify in writing each ACO of its determination of the amount of advance investment payment it will receive and that such notice would inform the ACO of its right to request reconsideration review.

- **Update Shared Savings Program Eligibility Requirements**

CMS is finalizing the proposal to limit the options for ACOs to request an exception to the requirement specified in § 425.106(c)(3) that 75 percent control of the ACO's governing body must be held by ACO participants.

CMS is finalizing without modification the proposal to codify the current operational approach for determining whether an ACO participant has participated in a performance-based risk Medicare ACO initiative. Under the current operational approach, an ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if its TIN was or will be used to calculate financial reconciliation for the entity participating in such ACO initiative. In general, if an ACO participant was included on an Initiative ACO's participant list for a performance year during the 5 most recent performance years before the ACO's agreement start date, and the Initiative ACO is, or will be, financially reconciled for that performance year, the ACO participant will be considered to have participated in the Initiative ACO.

CMS is also finalizing the proposal to modify the existing definitions for "experienced with performance-based risk Medicare ACO initiatives" and "inexperienced with performance-based risk Medicare ACO initiatives" at § 425.20 to include the following new sentence at the end of each definition: "An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for a performance year under such initiative during any of the five most recent performance years" effective on January 1, 2024.

CMS is finalizing the proposal to correct the error in the definition for "Rural health center (RHC)" at § 425.20 by replacing the word "center" with the word "clinic".

**Background/Rationale**

In combination, the above MSSP proposals are anticipated to improve the incentive for ACOs to sustainably participate and earn shared savings in the program. On net, total program spending is estimated to decrease by $330 million over the 10-year period 2024 through 2033. These changes are anticipated to support the goals outlined in the CY 2023 PFS final rule for growing the program with a particular focus on including underserved beneficiaries.

- **Revise Quality Reporting and Quality Performance Requirements**

Medicare CQMs would serve as a transition collection type to help some ACOs build the infrastructure, skills, knowledge, and expertise necessary to report all payer/all patient MIPS CQMs and eCQMs by defining a population of beneficiaries that exist within the all payer/all patient MIPS CQM Specifications and tethering that population to claims encounters with ACO professionals with specialties used in assignment.

The definition for beneficiary eligible for Medicare CQMs is intended to create alignment with the all payer/all patient MIPS CQM Specifications. The HCPCS and revenue center codes designated under § 425.400(c) as primary care services for purposes of assignment under the Shared Savings Program only partially over-lap with the codes designated as eligible encounters used to identify the eligible population in all payer/all patient MIPS CQM Specifications. Additionally, only applying the 12-month period used in assignment or deferring to the basic assignment methodology under Subpart E to identify the beneficiaries eligible for Medicare CQMs would have the unintended result of reducing the beneficiaries eligible for Medicare CQMs to only patients that had an eligible encounter during the overlap of the assignment window as defined at § 425.20 and the measurement period as defined in the Medicare CQM Specifications.

CMS believes establishing the Medicare CQM collection type would address the concerns from ACOs regarding the capability of meeting the data completeness requirement for all payer data. Specifically, the proposal to define Beneficiaries eligible for Medicare CQMs aims to focus ACOs' reporting efforts on beneficiaries with an encounter with an ACO professional with a specialty used in assignment and thereby reduce the potential for missing or un-matched patient data.

CMS also believes the Medicare CQMs rule is intended to support ACOs through the transition to reporting the all payer/all patient eCQMs/MIPS CQMs and to facilitate quality assessment improvement activities since we would provide ACOs with a list of beneficiaries eligible for Medicare CQM reporting to aid in patient matching and data deduplication.

- **Expanding the Health Equity Adjustment to Medicare CQMs**

Under the goals of the CMS National Quality Strategy, CMS is moving towards a building-block approach to streamline quality measures across CMS quality programs for the adult and pediatric populations. This "Universal Foundation" of quality measure will focus provider attention, reduce burden, identify disparities in care, prioritize development of interoperable, digital quality measures, allow for cross-comparisons across programs, and help identify measurement gaps.

The goal of the health equity adjustment is to reward ACOs serving a high proportion of underserved beneficiaries, with high performance scores on quality measures, and support ACOs with the transition to eCQMs/MIPS CQMs.

CMS believes that applying the health equity adjustment to an ACO's quality performance category score when reporting Medicare CQMs would encourage ACOs to treat underserved populations.

The underserved multiplier is a proportion ranging from zero-to-one of the ACO's assigned beneficiary population for the performance year that is considered underserved based on the highest of:

1. the proportion of the ACO's assigned beneficiaries residing in a census block group with an Area Deprivation Index (ADI) national percentile rank of at least 85; or
2. the proportion of the ACO's assigned beneficiaries who are enrolled in Medicare Part D low-income subsidy (LIS) or are dually eligible for Medicare and Medicaid.

The use of both the ADI and Medicare and Medicaid dual eligibility or LIS status to assess underserved populations in the health equity adjustment allows CMS to consider both broader neighborhood level characteristics and individual characteristics among CMS beneficiaries.

Removal of beneficiaries without a national percentile ADI rank from the health equity adjustment is more equitable because it will remove a beneficiary without an ADI rank from the denominator and the numerator of the calculation of an ACO's underserved multiplier instead of penalizing ACOs that have such beneficiaries.

CMS believes using the number of beneficiaries instead of person years would bring greater consistency between the two proportions used in determining the

underserved multiplier. It also acknowledges that beneficiaries with partial year as compared to 546 full year LIS enrollment or dual eligibility are also socioeconomically vulnerable and strengthens incentives for ACOs to serve this population. Further, inclusion of beneficiaries with partial year LIS enrollment in the underserved multiplier provides increased incentive for ACOs to help facilitate LIS enrollment for beneficiaries who meet eligibility criteria.

CMS believes using a 3-year historical average for base years would mitigate issues that may arise from using a single year historical reference such as scoring, policy, and/or performance anomalies, such as a pandemic, specific to the historical base year.

- **Proposals to Align CEHRT Requirements for Shared Savings Program ACOs with MIPS**

CMS believes that incorporating MIPS PI performance category's requirements into the Shared Savings Program will alleviate the burden that the current policy creates for ACOs. Because the Shared Savings Program CEHRT attestation requirement and the MIPS PI category requirements are not the same, ACOs have the burden of managing compliance with two different CEHRT program requirements.

- **Revise the Policies for Determining Beneficiary Assignment**

CMS believes the use of an expanded window for assignment in an enhanced stepwise assignment methodology would result in a greater overall number of beneficiaries assigned to ACOs. All beneficiaries who are assigned to an ACO under the current methodology would continue to be assigned to an ACO under the proposed methodology. Under the proposed methodology, a beneficiary who does not meet the current pre-step requirement would also be eligible to be assigned to an ACO if they (a) received at least one primary care service from a nurse practitioner, physician assistant, or clinical nurse specialist who is an ACO professional in the ACO during the applicable assignment window and (b) received at least one primary care service from a primary care physician or physician with a specialty used in assignment who is an ACO professional in the ACO during the applicable expanded window for assignment.

- **Revise the Policies on the Shared Savings Program's Benchmarking Methodology**

CMS believes the policy update to the regional update factor would help increase for ACOs operating in regional service areas with high-risk score growth, including those serving more medically complex beneficiaries, therefore increasing incentives for ACOs to form or continue participation in such areas. At the same time, CMS believes that incorporating the market share adjustment helps to mitigate concerns related to coding intensity for ACOs with high market share and thus a relatively high level of influence over risk scores in the ACOs regional service area.

CMS believes the adoption of the alternative approach to calculating prospective HCC risk scores for the performance year and each benchmark year of an ACO's agreement period would allow CMS to measure the change more accurately in severity and case mix for an ACO's assigned beneficiary population or the assignable beneficiary population. Under such an approach, there would be no potential for distortion from using different CMS-HCC risk adjustment models in calculating prospective HCC risk scores for benchmark years and the performance year that could occur under the current policy.

- **Modify AIP Recoupment and Recovery Policies for Early Renewing ACOs**

CMS believes that the Advance Investment Payment changes would help ensure that CMS efficiently obtains information in a consistent manner from all ACOs receiving advance investment payments and thereby support CMS's monitoring and analysis of the use these payments. CMS believes that these proposed changes will impose little to no administrative burden on participating ACOs, which are already required to publicly report this information by § 425.308(b)(8).

- **Update Shared Savings Program Eligibility Requirements**

CMS continues to believe that ACO participants should drive ACO leadership to move toward improved quality of care and patient outcomes, and that this is a key component of ACO success and ability to earn shared savings. The 75 percent participant control threshold is critical to ensuring that governing bodies are participant-led and best positioned to meet program goals, while allowing for partnership with non-Medicare enrolled entities to provide needed capital and

infrastructure for ACO formation and administration. Over the years, a few ACOs have requested an exception to form a governing body with less than 75 percent participant control. CMS discussed the exemption requests with the interested ACOs and ultimately the ACOs adjusted comply with the 75 percent participant control requirement. To date, CMS has not granted an ACO an exception to this requirement, despite the flexibility provided in current regulation. Accordingly, CMS believes that there is no reason to continue to offer an exception to the requirement, as ACOs have demonstrated that they can appropriately meet the 75 percent participant control requirement without utilizing this flexibility since its establishment in the November 2011 final rule.

## K. Medicare Part B Payment for Preventive Vaccine Administration Services (section III.H.)

**Finalized Changes**

CMS finalized as proposed to maintain the additional payment for the administration of a COVID-19 vaccine in the home and extend to include the other three preventive vaccines included in the Part B preventive vaccine benefit (pneumococcal, influenza, and hepatitis B vaccines), and the payment amount for all four vaccines would be identical. Beginning January 1, 2024, Medicare Part B will pay the same additional payment amount to providers and suppliers that administer a pneumococcal, influenza, hepatitis B, or COVID-19 vaccine in the home, under certain circumstances.

This additional payment amount will be annually updated using the percentage increase in the Medicare Economic Index (MEI) and adjusted to reflect geographic cost variations using the MPFS Geographical Adjustment Factor (GAF). CMS finalized that with the MEI percentage increase of 4.6%, the CY 2024 in-home additional payment for Part B preventative vaccine administration is being raised to $38.55. CMS finalized their proposal to limit the additional payment to one payment per home visit, even if multiple vaccines are administered during the same home visit.

**Background/Rationale**

CMS has updated their language surrounding what a home is classified as and the reasons a recipient would be unable to leave that home to receive a vaccination. Due

to these classifications, this add-on payment for in-home COVID-19 vaccine administration allows for those with disabilities and geographical barriers to get vaccinations without facing significant challenges in arriving to a clinic or facility outside of their home. There has been significant data to suggest that the coverage of other vaccinations has greatly increased the rate of vaccination in these communities. The additional payment for the COVID-19 vaccination will allow for a significant increase of vaccines for those in at-risk communities.

## L. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD Plan (section 2003 of the SUPPORT Act) (section III.M.)

**Finalized Changes**

- **CMS EPCS Program Terminology**

CMS finalized the use of the following terms to provide consistency and clarity throughout the CMS EPCS Program and future rules.

- CMS EPCS Program and the program requirements for PECS at § 423.160(a)(5) will be referred as the "CMS EPCS Programs."
- CMS will use "non-compliance action" or "action for non-compliance" to refer to a consequence for not meeting the CMS EPCS Program compliance threshold.
- CMS will use "measurement year" to describe the time period beginning on January 1 and ending on December 31 of each calendar year during which data is collected to calculate outcomes for the CMS EPCS Program.
- The CMS EPCS Program will use the phrase, "compliance threshold" in respect to the requirement that prescribers must conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances.
- CMS will use the "compliance analysis period" to refer to the time period after the measurement year when data is analyzed to determine whether prescribers have met the compliance threshold of the program.
- CMS will use the "notification period" to address the time period during which they will notify a prescriber of the prescriber's initial compliance status.

- CMS will use the phrase the "measurement cycle" to describe a period of 24 months.

- **Standards for Same Legal Entity**

CMS finalized their proposal to move the Medicare Program; E-Prescribing and Prescription Drug Program final rule (70FR 67581) to § 423.160(a)(3)(iii) in the CY 2008 PFS final rule (72 FR 66405). CMS removed the same entity exception at § 423.160(a)(5)(i) from the CMS EPCS Program requirement and redesignated paragraphs (a)(5)(ii) through (iv) as paragraphs (a)(5)(i) through (iii) and finalized the proposal to add "subject to the exemption in paragraph (a)(3)(iii) of this section" to § 423.160(a)(5) which will cause prescriptions that are prescribed and dispensed within the same legal entity to be included in CMS EPCS Program compliance calculations as part of the 70% compliance threshold at § 423.160(a)(5).

- **Definition of Prescriptions for Compliance Calculation**

CMS finalized specification on how the compliance threshold is affected by multiple fills within the same year, counting unique prescriptions in the measurement year using the prescription number assigned by the pharmacy and including this in the Part D claims data. All prescriptions regardless of how they are transmitted will now be able to include a number of refills so that the pharmacy may provide additional refills of the prescribed medication without the need to contact the prescriber for a new prescription form. CMS is counting renewals as an additional prescription in the CMS EPCS Program compliance threshold calculation and will not count refills as an additional prescription in the CMS EPCS Program compliance threshold calculation unless the refill is the first occurrence of the unique prescription. CMS will only count the unique prescription in the measurement year for the purposes of CMS EPCS Program compliance threshed calculations.

- **Updates to CMS EPCS Program Exceptions for Cases of Recognized Emergencies and Extraordinary Circumstances**

CMS finalized their proposal as it relates to applying for an exception versus having an automatic exception for all prescribers in an affected region, streamlining

communication across CMS programs and ensuring CMS can except all prescribers for an appropriate circumstance beyond their control, including disasters or emergencies.

CMS finalized their proposal to modify the definition of "extraordinary circumstance" to mean a situation outside of the control of a prescriber that prevents the prescriber from electronically prescribing a Schedule II-V controlled substance that is a Part D drug and will drop the restriction "other than an emergency or disaster" that was previously included in the exception. CMS will allow prescribers the ability to request a waiver regardless of whether they trigger the recognized emergency exception. CMS is permitting prescribers greater certainty that, regardless of whether they recognize an emergency under the exception at § 423.160(a)(5)(ii), a prescriber can still request a waiver identifying the extraordinary circumstances preventing the prescriber from complying with the CMS EPCS Program requirements.

- **Duration of Recognized Emergency Exceptions**

CMS finalized that as a default, prescribers impacted by the CMS EPCS Program recognized emergency exception at § 423.160(a)(5)(iii) would be excepted for the entire measurement year, and not just for the duration of the emergency, protecting prescribers who may not be able to monitor their compliance status over multiple periods of time, reducing administrative burden.

- **Duration and Timing of Extraordinary Circumstances Waiver Exception**

CMS finalized the ability for a prescriber to describe the reasons for non-compliance when they will not be able to apply for waivers until after the measurement period has ended. CMS finalized that a prescriber has a period of 60 days from the date of the notice of non-compliance to request a waiver and that the waiver would expire on December 31 of the applicable measurement year.

- **Actions for Non-Compliance**

CMS will send notices of non-compliance for each measurement year a prescriber is non-complaint and will provide educational opportunities to support prescribers in

becoming complaint. CMS will monitor CMS EPCS program compliance rates and may revisit the use of further non-compliance actions in future rulemaking.

**Background/Rationale**

- **CMS EPCS Program Terminology**

CMS found that the use of varying terminology to describe different requirements of EPCS left prescribers and other parties unclear. CMS changed these phrases and went with specific terminology in order to best provide consistency and clarity throughout the CMS EPCS Program and future rules, using this language going forward with future rules.

- **Standards for Same Legal Entity**

In an effort to better clarify the new NCPDP SCRIPT standards and CMS EPCS Program requirements, CMS is updating this proposal to be finalized. CMS is also providing clarification for Medicare Part D standards for electronic prescribing and aligning these standards with the rest of the Medicare programs. The integration of the regulation into the CMS EPCS Program provides better and clearer guidelines in respect to the SCRIPT standard.

- **Definition of Prescriptions for Compliance Calculation**

CMS updated their proposal to address that the compliance threshold is affected by multiple fills within the same year, counting unique prescriptions in the measurement year using the prescription number assigned by the pharmacy and including this in the Part D claims data. CMS is addressing the concern of administrative burden placed on small prescribers.

- **Updates to CMS EPCS Program Exceptions for Cases of Recognized Emergencies and Extraordinary Circumstances**

CMS is conducting this final rule change in order to best align CMS practices with one another in an effort to streamline the communication channels across the various programs. By defining these terms, CMS is making an effort to define what an emergency is and to be able to best conduct this across programs.

- **Duration of Recognized Emergency Exceptions**

CMS through this proposal will be recognizing emergences and their impacts on the communities that they impact. CMS realized that they can identify emergencies recognized by FEMA and HHS but not by state and local emergency departments, causing there to be concerns with prescribers to conduct EPCS and that there may be concerns here. This final change addresses this.

- **Duration and Timing of Extraordinary Circumstances Waiver Exception**

In an effort to continue aligning the CMS EPCS Program with the Quality Payment Program, prescribers impacted by the CMS EPCS Program recognized emergency exception, the regulation in this rule would be expected for the entire measurement year and not just the duration of the emergency. After soliciting comments, CMS believes that this will best protect small prescribers.

- **Actions for Non-Compliance**

CMS believes that it will support the rules outlined in support of EPCS adherence, and this will reduce administrative burdens for their services.

## M. Hospice: Changes to the Hospice Conditions of Participation (section III.O.)

**Finalized Changes**

CMS finalized the provision regarding the inclusion of a MFT and MHC in the hospice IDG with modification at § 418.56 by removing the phrase "depending on the preferences and needs of the patient." CMS also clarified the provision by redesignating the personnel qualifications at § 418.114(c)(3) and (4) to § 418.114(b)(9) and (10) referencing requirements at §§ 410.53 and 410.54, respectively. The inclusion of a MFT and MHC in the personnel requirements will clarify for hospices the qualifications required for MFT and MHC.

**Background/Rationale**

CMS believes this modification will provide additional flexibility for the hospice to choose the members of the IDG while also utilizing the hospice's system of communication to ensure information is communicated during the IDG meetings, according to the hospices own policies. The inclusion of an MFT or MHC as members

of the hospice IDG helps to provide hospices with greater flexibility in IDG membership in meeting the mental health needs of their patients. The provisions support CMS's responsibility to protect patient health and safety by encouraging the patients' and their family members to act as active participants in decision-making processes.

## N. Social Determinants of Health Risk Assessment in the Annual Wellness Visit (section III.S.)

**Finalized Changes**

CMS finalized their proposal to pay separately for a Social Determinants of Health (SDOH) Risk Assessment. The finalized SDOH Risk Assessment will be:

- Separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the annual wellness visit (AWV).
- Able to be furnished over a period of multiple days.
- Paid 100 percent of the fee schedule amount for the service.
- Inclusive of the administration of a standardized, evidence based SDOH risk assessment tool.
- Optional for both the health professional and the patient as to allow discretion to use the tool when needed.
- Furnished in a manner that all communication with the patient be appropriate for the patient's educational, developmental, and health literacy level, and be culturally and linguistically appropriate.

**Background/Rationale**

CMS noted this aligns closely with HHS's Strategic Approach to Addressing Social Determinants of Health to Advance Health Equity, the CMS Strategic Pillar to promote equity, and the CMS Innovation Center's Accountable Health Communities (AHC) Model that concluded in 2022. CMS is also mindful of concerns about AWV completion barriers, its one-size-fits-all approach, and research indicating that underserved patients and practices serving vulnerable populations may face challenges in accessing AWV services.

CMS received feedback from commenters that shared concerns about the feasibility of completing an SDOH Risk Assessment and an AWV in the same day. It is because

of this that they have allowed for elements of the assessment to be furnished prior to the AWV. CMS increasingly recognizes the importance of considering SDOH in the care process and anticipates that this finalized rule will alleviate barriers, enhance access, foster health equity, and enhance care for historically underserved populations.

## O. Updates to the Quality Payment Program (section IV.)

**Finalized Changes**

- **Development and Maintenance of MIPS Value Pathways (MVPs)**

CMS finalized their proposal to add 5 new MVPs for the 2024 performance year. There will be a total of 16 MVPs available for reporting in the 2024 performance period. The 5 new MVPs are:

1. Focusing on Women's Health
2. Quality Care for the Treatment of Ear, Nose, and Throat Disorders
3. Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV
4. Quality Care in Mental Health and Substance Use Disorders
5. Rehabilitative Support for Musculoskeletal Care

- **Third Party Intermediaries**

CMS finalized their proposal to eliminate the health IT vendor category beginning with the CY 2025 performance period. In order to submit data on behalf of clinicians, a health IT vendor would need to meet the requirements of and self-nominate to become a qualified registry or QCDR. They can continue to facilitate data collection and support clinicians and groups in the sign in and upload and sign in and attest submission types.

CMS finalized their proposal to clarify that a QCDR or a qualified registry must support all measures and improvement activities available in the MVP with 2 exceptions:

1. If an MVP includes several specialties, then the QCDR or qualified registry is only expected to support the measures that are pertinent to the specialty of their clinicians.

2. QCDR measures are only required to be reported by the QCDR measure owner. In instances where a QCDR doesn't own the QCDR measures in the MVP, the QCDR can only support the QCDR measures if they have the appropriate permissions.

CMS finalized the following policies related to third party intermediaries:

1. CMS will indicate in the public qualified postings that a third-party intermediary has been placed on a remedial action plan or terminated.
2. CMS can take remedial action, including termination, for third party intermediaries that fail to maintain up-to-date contact information.
3. Third party intermediaries will be required to notify CMS when a CAP has been successfully completed.
4. CMS can initiate termination of third-party intermediaries that are on remedial action for two consecutive years.

- **Public Reporting**

CMS finalized their proposal to modify existing policy about publicly reporting procedure utilization data on individual clinician profile pages by incorporating Medicare Advantage (MA) data.

- **Quality Performance Category**

CMS finalized changes to the quality measures inventory resulting in a total of 198 quality measures for the 2024 performance period. The changes reflect the addition of 11 quality measures including 1 composite measure and 6 high priority measures, of which 4 are patient-reported outcome measures. It also includes the removal of 11 quality measures, partial removal of 3 quality measures, and substantive changes to 59 existing quality measures.

CMS did not finalize an increase to the data completeness threshold for the 2027 performance period. The Agency finalized to maintain the data completeness threshold of 75% for the 2026 performance period, which is applicable to eCQMs, MIPS CQMs, Medicare Part B claims measures, and QCDR measures.CMS also finalized the data completeness criteria threshold of 75% for Medicare CQMs for the 2024, 2025, 2026 performance periods.

CMS finalized their proposal to require groups, virtual groups, subgroups, and APM Entities (including Shared Savings Program ACOs) to contract with a CAHPS for MIPS survey vendor to administer the Spanish survey translation to Spanish-preferring patients using the procedures detailed in the CAHPS for MIPS Quality Assurance Guidelines.

- **Cost Performance Category**

CMS finalized their proposal to calculate improvement scoring for the cost performance category at the category level without using statistical significance beginning with the CY 2023 performance period/2025 MIPS payment year.

CMS finalized their proposal for the maximum cost improvement score of 1 percentage point out of 100 percentage points to be available beginning with the 2023 performance period. The maximum cost improvement score available for the 2022 performance period is 0 percentage points.

CMS finalized their proposal to add 5 new episode-based cost measures beginning with the CY 2024 performance period, each with a 20-episode case minimum. The measures are: an acute inpatient medical condition measure (Psychoses and Related Conditions), three chronic condition measures (Depression, Heart Failure, and Low Back Pain), and a measure focusing on care provided in the emergency department setting (Emergency Medicine). CMS also finalized their proposal to remove the acute inpatient medical condition measure Simple Pneumonia with Hospitalization, beginning with the CY 2024 performance period/2026 MIPS payment year.

- **Improvement Activities Performance Category**

CMS finalized their proposal to add 5 new improvement activities. These additions include an MVP-specific improvement activity titled "Practice-Wide Quality Improvement in MIPS Value Pathways".

- **Promoting Interoperability Performance Category**

CMS finalized their proposal to update the CEHRT definition to align with the Office of the National Coordinator for Health IT (ONC)'s regulations.

CMS finalized their proposal to continue automatic reweighting for clinical social workers in the 2024 performance period.

CMS finalized their proposal to increase the performance period to a minimum of 180 continuous days within the calendar year.

CMS finalized our proposal to require a "yes" response on the attestation for the SAFER Guide measure beginning with the CY 2024 performance period. Clinicians only need to review the High Priority Practices SAFER guide.

- **Final Scoring**

CMS finalized their policy to clarify that they will not calculate a facility-based score at the subgroup level. Facility-based scores are only calculated as part of a final score in traditional MIPS* which isn't an available reporting option for subgroups.

CMS finalized their policy to clarify that beginning with the 2023 performance period/2025 MIPS payment year, subgroups would receive their affiliated group's complex patient bonus, if available.

CMS did not finalize their proposal to increase the performance threshold from 75 to 82 points for the 2024 MIPS performance period/2026 MIPS payment year. The performance threshold will remain 75 points.

Beginning with the 2024 performance period, the targeted review submission period will open upon release of MIPS final scores and remain open for 30 days after MIPS payment adjustments are released. This will maintain an approximately 60-day period for requesting a targeted review: 30 days before payment adjustments are released and 30 days after payment adjustments are released.

CMS finalized their proposal that, if CMS requests additional information under the targeted review process, that additional information must be provided to and received by CMS within 15 days of receipt of such request.

CMS finalized that subgroups and virtual groups will be added to the list of entities that may submit a request for a targeted review for the MIPS payment adjustment factor beginning with the 2023 performance period.

- **Advanced APMs**

CMS finalized their proposal to remove the numerical 75% threshold and have the Advanced APM require the use of the certified electronic health record technology

(CEHRT) for Qualifying APM Participant (QP). However, CMS is finalizing this proposal with a one-year delay to the 2025 performance year.

CMS didn't finalize the proposal to make QP determinations at the individual eligible clinician level only, instead of the APM Entity level.

Under current statute, the QP threshold percentages will increase beginning with the 2024 performance year/2026 payment year.

1. Medicare payments:
    a. QP threshold increasing from 50% to 75%
    b. Partial QP threshold increasing from 40% to 50%
2. Medicare patients:
    a. QP threshold increasing from 35% to 50%
    b. Partial QP threshold increasing from 25% to 35%

Beginning for the 2024 performance year/2026 payment year, QPs will receive a higher MPFS update ("qualifying APM conversion factor") of 0.75% compared to non-QPs, who will receive a 0.25% Medicare PFS update, which will result in a differentially higher PFS payment rate for eligible clinicians who are QPs. Eligible clinicians who are QPs for a year will continue to be excluded from MIPS reporting and payment adjustments for the year.

**Background/Rationale**

- **Development and Maintenance of MVPs**

CMS noted that they are implementing MVPs to allow clinicians to report on measures that are directly relevant to their clinical practice. MVPs provide more clinically relevant performance measurement, engage more specialists in performance measurement, and reduce barriers to APM participation.

- **Public Reporting**

CMS highlighted that publicly reporting Medicare Advantage (MA) data, in addition to Medicare FFS utilization data counts, as appropriate and technically feasible, can help address low volume counts and provide a more complete scope of a clinician's experience.

- **Cost Performance Category**

CMS noted that this updated methodology will ensure mathematical and operational feasibility to allow for improvement to be scored in the cost performance category starting with the 2023 performance period/2025 MIPS payment year. This update also aligns with their methodology for scoring improvement in the quality performance category.

- **Improvement Activities Category**

CMS stated that the new and modified activities help fill gaps they have identified in the Inventory as well as seek to ensure that activities reflect current clinical practice across the category. CMS highlighted that the new improvement activity allows clinicians to receive full credit in this performance category for adopting a formal model for quality improvement related to a minimum of 3 of the measures reported as part of a specific MVP.

- **Promoting Interoperability Performance Category**

CMS noted that in a recent proposed rule, ONC proposed to move away from the "edition" construct for certification criteria. Instead, all certification criteria will be maintained and updated at 45 CFR 170.315. The Agency is aligning their definitions of CEHRT for QPP and the Medicare Promoting Interoperability Program with the definitions and requirements ONC currently has in place and may adopt in the future.

CMS stated that the increase of the performance period to a minimum of 180 days ensures that the MIPS Promoting Interoperability performance category continues to align with the Medicare Promoting Interoperability Program for eligible hospitals and critical access hospitals.

- **Final Scoring**

CMS noted that the Agency didn't finalize their proposal to use the mean of final scores from the 2017 – 2019 performance periods to set the MIPS performance threshold, which would have increased the performance threshold to 82 points.

CMS stated that this updated timeline will allow us to ensure that we have completed adjudicating targeted reviews and have a finalized list of Qualifying APM Participants (QPs) by October 1 so that accurate payments reflective of performance across QPP

(that is, MIPS payment adjustments and the Qualifying APM conversion factor) can be implemented as of January 1 of the payment year.

CMS highlighted that their policy for targeted review requests will support their ability to finalize scores and QP status by October 1.

## P. Regulatory Impact Analysis (section VII.)

**Finalized Changes**

The final CY 2024 PFS conversion factor is $32.74, a decrease of $1.15 (or 3.4%) from the current CY 2023 conversion factor of $33.89.

**TABLE 116: Calculation of the CY 2024 PFS Conversion Factor**

| | | |
|---|---|---|
| CY 2023 Conversion Factor | | 33.8872 |
| Conversion Factor without the CAA, 2023 (2.5 Percent Increase for CY 2023) | | 33.0607 |
| CY 2024 RVU Budget Neutrality Adjustment | -2.20 percent (0.9780) | |
| CY 2024 1.25 Percent Increase Provided by the CAA, 2023 | 1.25 percent (1.0125) | |
| **CY 2024 Conversion Factor** | | **32.7375** |

*RVUs*: Table 118 (CY 2024 PFS Estimated Impact on Total Allowed Charges by Specialty) on page 1950 of the proposed rule summarizes the impact of Work, PE, and MP RVU changes on total allowed charges across specialties.

*Facility vs. Non-Facility Break Out of Payment Changes*: Note, for the 2024 MPFS rulemaking cycle, beginning on page 1953, CMS is providing in Table 119 (CY 2024 PFS Estimated Impact on Total Allowed Charges by Setting) more granular information that separates the specialty-specific impacts by site of service in response to concerns that Medicare payment policies are directly responsible for the consolidation of privately owned physician practices and free standing supplier facilities into larger health systems.