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Regulatory Update: Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements

July 30, 2021

Background & Summary

On Tuesday, July 13, the Centers for Medicare & Medicaid Services (CMS) issued the annual proposed rule to update the Calendar Year (CY) 2022 Medicare payment and policies for the Physician Fee Schedule (PFS). The Proposed Rule revises payment polices under the Medicare PFS and makes other policy changes, including proposals to extend access to certain telehealth services provided during the COVID-19 Public Health Emergency (PHE) and implementation of the telehealth provisions in the Consolidated Appropriations Act, 2021 for mental health services. The PFS Addenda, along with supporting documents and tables referenced in the Proposed Rule, are available on the CMS website. The Proposed Rule also includes changes to the Quality Payment Program (QPP).

Comments are due **September 13, 2021**, with effective dates for most sections scheduled for January 1, 2022. Vizient looks forward to working with members to help inform our comments to the agency.

Calculation of the Proposed CY 2022 PFS Conversion Factor

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

PFS Payment = [(Work RVU x Work GPCI) + (PE RVU x PE GPCI) + (MP RVU x MP GPCI)] x CF

For CY 2022, CMS proposes to decrease the CF by .14 percent to maintain budget neutrality. As described in the below table, the proposed 2022 CF is 33.5848 (a decrease of 1.3083 from the 2021 CF of 34.8931).

Calculation of the Proposed CY 2022 PFS Conversion Factor		
CY 2021 Conversion Factor		**34.8931**
Conversion Factor without CY 2021 Consolidated Appropriations Act's 3.75 percent increase		**33.6319**
Statutory Update Factor	0.00 percent (1.0000)	
CY 2022 RVU Budget Neutrality Adjustment	-0.14 percent (0.9986)	
CY 2022 Conversion Factor		**33.5848**

Determinations of Practice Expense Relative Value Units

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

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

Generally, CMS proposes limited changes to the PE RVU methodology. The agency has provided a file, "Calculation of PE RVUs under Methodology for Selected Codes", which illustrates the calculation of PE RVUs as described in the Proposed Rule for individual codes. To determine the PE RVU, there are direct PE inputs for specific services which are included in the CY 2022 direct PE input public use files that are available on the CMS Website.

In the Proposed Rule, CMS aims to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database, instead of only including the sum of the number of clinical labor minutes for the preservice, service, and post service periods for each code. For CY 2022, CMS continues to display two versions of the Labor Task Detail public use file: one version with the old listing of clinical labor tasks and one with the same tasks crosswalked to the new listing of clinical labor activity codes. The files are available on the CMS website.

For CY 2022, CMS proposes to update clinical labor pricing as clinical labor rates were last updated in 2002. CMS proposes to continue to rely on a methodology outlined in the CY 2002 PFS final rule to calculate labor pricing. Table 5 (pg. 51-52) of the Proposed Rule lists the proposed updates to clinical labor prices. **CMS solicits comments on the proposed updated clinical labor pricing and is particularly interested in additional wage data for the clinical labor types for which the agency lacks direct Bureau of Labor Statistic (BLS) wage data and, rather, made use of proxy labor categories for pricing.** CMS notes it did consider a potential 4-year transition for the clinical labor pricing update as an alternative.

In the CY 2019 PFS, CMS finalized a policy to update the PFS direct practice expense inputs (DPEI) for supply and equipment pricing, to be phased in over 4 years. For CY 2022, CMS proposes to update the price of six supplies and two equipment items in response to the public submission of invoices. Since this is the final year of the supply and equipment pricing update, the new pricing for each of these supply and equipment items will take effect for CY 2022. The six supply and equipment items with proposed updated prices are listed in the valuation of specific codes in Table 16 of the Proposed Rule (pg. 239).

Telehealth and Other Services Involving Communications Technology, and Interim Final Rule with Comment Period for Coding and Payment of Virtual Check-in Services – Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

Several conditions (e.g., patient eligibility, telehealth services, originating sites, distant site practitioners, interactive telecommunications system) must be met for Medicare to make payments for telehealth services under the PFS. Other services involving communications technology (e.g., remote evaluation of recorded video and/or images submitted by an established patient, brief

communication technology-based service (CTBS), online assessment and management) are also covered under the PFS but are different from telehealth services. During the PHE and in the CY 2021 PFS Final Rule, CMS expanded access to both telehealth and other services involving communications technology, among other changes, which the agency addresses in the CY 2022 Proposed Rule.

Medicare Telehealth Service List

CMS maintains a Medicare telehealth services list and has a long-standing process for adding or deleting services from the list.[1] Under this process, CMS receives requests from the public for adding services and assigns requests to one of two categories: Category 1 (services similar to professional consultations, office visits, and office psychiatry service currently on the Medicare telehealth services list) or Category 2 (services that are not similar to those currently on the Medicare telehealth services list and require additional evidence for telehealth reimbursement). In the CY 2021 PFS Final Rule, CMS created a third category (Category 3) of criteria for adding services to the telehealth list on a temporary basis following the end of the COVID-19 Public Health Emergency (PHE).

Requests to Add Services to the Medicare Telehealth Services List for CY 2022

For CY 2022, CMS received several requests to permanently add various services to the Medicare telehealth services list. However, CMS indicates none of the requests were received by the February 10 submission deadline for Category 1 or Category 2 criteria for permanent addition. Table 8 of the Proposed Rule (pg. 83) lists the services requested to be made permanently available. However, CMS is not proposing to add the services permanently to the telehealth list because it did not find that the requested services met the Category 1 or 2 criterion.

In addition, CMS received requests to permanent add four services (Table 9, pg. 89) that are not generally separately payable under the Medicare PFS or are adjudicated on a case-by-case basis. Since the services are not separately payable when furnished in-person, CMS indicates they would not be separately payable when furnished as telehealth, and therefore, the agency declined to add the services to the telehealth list.

CMS also received requests to add services to the telehealth services list on a Category 3 basis. CMS notes these services (i.e., Neurostimulators and Neurostimulators Analysis Programming) are on the expanded telehealth services list for the PHE but were not added by CMS on a category 3 basis in the CY 2021 PFS final rule. Due to a lack of data, CMS is not proposing to add these services to the telehealth list on Category 3 basis, but requests commenters submit all available information for future consideration.

Revised Timeframe for Consideration for Services Added to the Telehealth List on a Temporary Basis

In the CY 2021 PFS Final Rule, CMS indicated any services added on a temporary basis under Category 3 would remain on the Medicare telehealth services list through the end of the calendar year in which the PHE for COVID-19 ends. To respond to stakeholder concerns regarding uncertainty of the duration of the COVID-19 PHE, CMS proposes to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023.

Notably, not all telehealth services available during the PHE will be available until the end of CY 2023. Table 11 of the Proposed Rule (pg. 93-100) provides a list of services that were added to the

[1] 1834(m)(4)(F)(ii) of the Social Security Act

Medicare telehealth services list on an interim basis to respond to the PHE but were not previously extended on a Category 3 basis. Under CMS's current policy, these services will be removed from the Medicare telehealth services list as of the date that the PHE for COVID-19 ends. **CMS is soliciting comment on whether any of the services that were added to the Medicare telehealth list for the duration of the PHE for COVID-19 should now be added to the Medicare telehealth list on a Category 3 basis.**

Implementation of Provisions of the Consolidated Appropriations Act, 2021 Pertaining to Medicare Telehealth Services

The Medicare telehealth statute generally limits the scope of telehealth services to those furnished in rural areas and in certain enumerated types of "originating sites", including physician offices, hospitals and other medical care settings. However, there is an exception to the geographic restriction with the patient's home as an allowable originating site for telehealth services furnished to a patient with a diagnosed substance use disorder (SUD) for treatment of that disorder or a co-occurring mental health disorder. The Consolidated Appropriations Act, 2021 (CAA) permanently broadened the scope of services for which the geographic site restriction does not apply and for which the patient's home is a permissible originating site. Specifically, the scope of telehealth services now includes services furnished for the purpose of diagnosis, evaluation, or treatment of a mental health disorder, effective for services furnished on or after the end of the COVID-19 PHE. In the Proposed Rule, CMS provides regulations implementing this change.

Notably, the CAA prohibited payment for these mental health services (other than for treatment of diagnosed SUD or co-occurring mental health disorder) unless the physician or practitioner furnishes an item or service in-person, without the use of telehealth, within the 6-month period[2] before the date of the telehealth service. The practitioner must distinguish between the telehealth and non-telehealth mental health services in the patient's medical record. **CMS seeks comment on whether the required in-person visit could also be furnished by another physician or practitioner of the same specialty and same subspecialty within the same group as the physician or practitioner who furnishes the telehealth service.**

In addition, CMS seeks comment on whether it should adopt a claims-based mechanism to distinguish between the mental health telehealth services that are within the scope of the CAA amendments and those that are not, and if so, what that mechanism should be.

Lastly, the CAA also amended the telehealth statute to add to the list of permissible telehealth originating sites a rural emergency hospital, which is also a new Medicare provider type (per the CAA) effective beginning CY 2023.

Payment for Medicare Telehealth Services Furnished Using Audio-Only Communications

The Medicare statute outlines the requirements for payment for telehealth services furnished via a "telecommunications system" with limited exceptions (i.e., a federal telemedicine demonstration program in Alaska or Hawaii). Through regulation, CMS has defined the term "telecommunications system," to mean an interactive telecommunications system, which is further defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. During the PHE, CMS used its waiver authority to permit audio-only telehealth services

[2] Given mental health services may be furnished on or after the first day of the end of the PHE, it is important to note that CMS clarifies payment will not be made for these mental health telehealth services unless the physician or practitioner has furnished an item or service in person, without the use of telehealth for which Medicare payment was made (or would have been made) within 6 months of the telehealth service.

for certain behavioral health and/or counseling services and for audio-only evaluation and management (E/M) visits. CMS clarifies that since emergency waiver authority will not be available after the PHE ends, telehealth services will again be subject to all statutory and regulatory requirements.

In the Proposed Rule, CMS is reconsidering its interpretation of "interactive telecommunications system" based on utilization data from the PHE, stakeholder feedback and beneficiary reliance on audio-only services. CMS proposes to amend its definition of interactive telecommunications system to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to established patients when the originating site is the patient's home. CMS proposes to adopt a requirement that an in-person item or service must be furnished within 6 months of such mental health telehealth services.

CMS is also proposing to limit payment for audio-only services to services furnished by physicians or practitioners who have the capacity to furnish two-way, audio/video telehealth services but are providing the mental health services via audio-only services because the beneficiary is unable to use, does not wish to use or does not have access to two-way, audio/video technology. To monitor utilization and program integrity concerns, CMS proposes to create a service-level modifier that would identify these mental health telehealth services furnished to a beneficiary in their home using audio-only communications technology. **CMS seeks comment on whether, for purposes of these audio-only service, it should exclude certain higher-level services (e.g., level 4 or 5 E/M codes when furnished alongside add-on codes for psychotherapy) and if any, documentation should be required in the patient's medical record to support the clinical appropriateness (e.g., for audits or claim denials) of providing audio-only telehealth services for mental health.**

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

Expiration of the PHE Flexibilities for Direct Supervision Requirements

Under Medicare statute and regulations, certain types of services must be furnished under specific level of supervision by a physician or practitioner, including diagnostic tests, services incident to physician services and other services.[3] During the PHE, CMS changed the definition of "direct supervision" as it pertains to supervision of diagnostic tests, physicians' services and some hospital outpatient services, to allow the supervising professional to be immediately available through virtual presence using real-time audio/video technology, instead of requiring their physical presence. In the CY 2021 PFS final rule, CMS finalized the continuation of this policy through the end of the calendar year in which the PHE for COVID-19 expires or December 31, 2021, whichever comes later.

In the Proposed Rule CMS to seek feedback on this policy, including the extent to which the flexibility to meet the immediate availability requirement for direct supervision through the use of real-time, audio/video technology is being used during the PHE and whether this flexibility will be useful after the PHE. **CMS also asks whether the agency should permanently revise the definition of "direct supervision" to include immediate availability through the virtual presence of the supervising physician or practitioner. CMS also seeks comment regarding the possibility of permanently allowing immediate availability for direct supervision through virtual presence for only a subset of services.**

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[3] For professional services furnished incident to the services of a billing physician or practitioner and many diagnostic tests, direct supervision is required. Additionally, for pulmonary rehabilitation services and for cardiac rehabilitation and intensive cardiac rehabilitation services, requirements for immediate availability and accessibility of a physician are considered to be satisfied if the physician meets the requirements for direct supervision for physician office services and for hospital outpatient services.

Brief Communication Technology-Based Services

In the CY 2021 PFS final rule, due to stakeholders voicing the need for coverage of audio-only conversations, CMS finalized the establishment of HCPCS code G2252 (*Brief communication technology-based service*[4]) on an interim basis. Given the need for additional time to assess the necessity of an in-person service, for CY 2022, CMS proposes to permanently adopt coding and payment HCPCS code G2252 as described in the CY 2021 PFS final rule.

Beneficiary Consent Under General Supervision

During the COVID-19 PHE, CMS allowed stakeholders to obtain beneficiary consent for certain services under general supervision. Before the PHE, CMS required that beneficiary consent be obtained either by or under the direct supervision of the primary care practitioner. As CMS considers what policies implemented during the PHE for COVID-19 should remain in effect beyond the PHE, CMS is interested in understanding how billing practitioners furnishing Chronic Care Management (CCM) at different service sites (for example, physician office settings, RHCs, FQHCs) have been obtaining beneficiary consent over the past year and how different levels of supervision impact this activity. **CMS is particularly interesting on what levels of supervision are necessary to obtain beneficiary consent when furnishing CCM services and will consider such comments in future rulemaking.**

Comment Solicitation on Separate PFS Coding and Payment for Chronic Pain Management

CMS recognizes that there are no existing codes that specifically describe the work of the clinician involved in performing the tasks necessary to perform pain management care. The agency also believes that creating separate or add-on payments for care and management for people with pain might provide opportunities to better leverage services furnished using telecommunications technology and non-face-to-face care while expanding access to treatment for pain. As such, **CMS solicits comment on whether it should consider creating separate coding and payment for medically necessary activities involved with chronic pain management and achieving safe and effective dose reduction of opioid medications when appropriate, or whether the resources involved in furnishing these services are appropriately recognized in current coding and payment.** In addition, the agency welcomes feedback on potential separate coding or an E/M add-on code for chronic pain management for consideration for CY 2022 or for future rulemaking.

Evaluation and Management Visits

Over the past several years, CMS has engaged with the American Medical Association (AMA) and other stakeholders in a process to update coding and payment for office/outpatient evaluation and management (E/M) visits, with recent changes taking effect January 1, 2021. CMS continues to review E/M policies and is proposing several refinements to the current policies regarding split (or shared) visits, critical care services and teaching physician visits.

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[4] Brief communication technology-based service for HCPCS code 2252 is a virtual check-in service, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion

Split (or Shared) Visits

A split (or shared) visit refers to an E/M visit that is performed ("split" or "shared") by both a physician and a non-physician practitioner (NPP) who are in the same group. In the Proposed Rule, CMS indicates that because the Medicare statute provides a higher PFS payment rate for services furnished by physicians than services furnished by NPPs, it needs to address whether and when the physician can bill for split (or shared) visits.

CMS proposes to define a split (or shared) visit as an E/M visit in the facility setting that is performed in part by both a physician and an NPP who are in the same group, in accordance with applicable laws and regulations. In addition, CMS proposes to limit the definition of split (or shared) visit to include only E/M visits in institutional settings, for which incident-to payment is not available. In addition, CMS proposes to allow physicians and NPPs to bill for split (or shared) visits for both new and established patients, and for critical care and certain Skilled Nursing Facility/ Nursing Facility (SNF/NF) E/M visits.

Notably, only the physician or NPP who performs the substantive portion of the split (or shared) visit would bill for the visit. CMS proposes to define "substantive portion" as more than half of the total time (not Medical Decision Making (MDM)) spent by the physician and NPP performing the visit. Also, CMS proposes that the distinct time of service spent by each physician or NPP furnishing a split (or shared) visit would be summed to determine total time and who provided the substantive portion (and therefore bills for the visit).

CMS proposes a listing of activities that could count toward total time for purposes of determining the substantive portion. For visits that are not critical care services, CMS is proposing the same listing of activities that can count when time is used to select E/M visit level, specifically the following activities, when performed and regardless of whether or not they involve direct patient contact:

- Preparing to see the patient (for example, review of tests)
- Obtaining and/or reviewing separately obtained history
- Performing a medically appropriate examination and/or evaluation
- Counseling and educating the patient/family/caregiver
- Ordering medications, tests, or procedures
- Referring and communicating with other health care professionals (when not separately reported)
- Documenting clinical information in the electronic or other health record
- Independently interpreting results (not separately reported) and communicating results to the patient/ family/caregiver
- Care coordination (not separately reported). Practitioners would not count time spent on the following:
    - The performance of other services that are reported separately
    - Travel
    - Teaching that is general and not limited to discussion that is required for the management of a specific patient

Since critical care services can include additional activities that are bundled into the critical care visit code(s), CMS proposes a different listing of qualifying activities. Additionally, **CMS seeks public comment on these proposals and on whether there should be a different listing of qualifying activities for purposes of determining the total time and substantive portion of split (or shared) emergency department visits.**

Application to Prolonged Services

CMS proposes to allow a practitioner to bill for a prolonged E/M visit as a split (or shared) visit. Specifically, the physician or practitioner who performed the substantive portion would bill for the primary E/M visit and the prolonged service code(s) when the service is furnished as a split (or

shared) visit, if all other requirements to bill for the services were met. The physician and NPP would sum their time together, and whomever furnished more than half of the total time, including prolonged time (that is, the substantive portion) would report both the primary service code and the prolonged services add-on code(s) (not the prolonged E/M service code).

Settings of Care and Same Group

CMS notes the concept of split (or shared) visits in the facility setting was developed to be comparable to payment policies for services and supplies furnished incident to a physician's or an NPP's professional services in the non-institutional setting. In the Proposed Rule, CMS proposes to allow billing of split (or shared) visits, including critical care visits, when they are performed in any institutional setting. In addition, CMS proposes that a physician and NPP must be in the same group for the physician and NPP to bill for a split (or shared) visit. However, if a physician and NPP are in different groups, CMS would expect the physician and NPP to bill independently, and only for the services they specifically and fully furnish. **CMS seeks comment on whether "group" should be further defined.**

Medical Record Documentation and Claim Identification

To ensure program integrity and quality of care, CMS is proposing to require that documentation in the medical record identifies the two individual practitioners who performed the visit. The individual who performed the substantive portion (and therefore bills the visit) would be required to sign and date the medical record.

CMS also proposes to create a modifier to describe split (or shared) visits, and the agency is proposing to require that the modifier be appended to claims for split (or shared) visits, whether the physician or NPP bills the visit. CMS notes that the modifier for reporting partial services (modifier -52 (reduced services)) cannot be used to report partial E/M visits (i.e., not all elements of the services are furnished). **CMS seeks comment on whether it should amend regulations to explicitly state that Medicare does not pay for partial E/M visits.**

Critical Care Services

Consistent with CMS's efforts to refine payment for office/outpatient E/M visits, CMS is proposing refinements to other E/M code sets, including critical care services. Critical care visits are described by CPT codes 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes) and 99292 (each additional 30 minutes (List separately in addition to code for primary service). Generally, CMS proposes to update the critical care E/M visit policies to improve transparency and largely aligning with 2021 CPT Codebook (E/M Services Guidelines). For example, CMS proposes to rely on the 2021 CPT Codebook (E/M Services Guidelines) for the definition of critical care, and critical care by a single physician or NPP.

CMS also proposes to adopt CPT's listing of bundled services that are part of critical care visits. As such, several services[5] would be bundled into critical care visits. As a result, these codes would not be separately billable by a practitioner during the time-period when the practitioner is providing critical care for a given patient.

In addition, in the Proposed Rule, CMS provides policies for a range of circumstances in which critical care services may be provided including: critical care services furnished by different

[5] The services are: interpretation of cardiac output measurements (93561, 93562), chest X rays (71045, 71046), pulse oximetry (94760, 94761, 94762), blood gases, and collection and interpretation of physiologic data (for example, ECGs, blood pressures, hematologic data); gastric intubation (43752, 43753); temporary transcutaneous pacing (92953); ventilator management (94002-94004, 94660, 94662); and vascular access procedures.

specialties; critical care services furnished concurrently by practitioners in the same specialty and same group for follow-up care to the same patient on the same day; critical care visits and same-day emergency department, inpatient or office/outpatient visits; and care visits and global surgery.

CMS also proposes that critical care visits may be furnished as split (or shared) visits. In addition, CMS is proposing a different list of qualifying activities for split (or shared) critical care (as described in the CPT Codebook). In contrast to CMS's proposals for other critical care services, CMS proposes that when a critical care service is furnished as a split (or shared) visit, when two or more practitioners spend time jointly meeting with or discussing the patient, the time may be counted only once for purposes of reporting the split (or shared) critical care visit. **CMS seeks comment on this proposal and indicates it intends to assess whether it should require that an individual physician or NPP directly perform the entirety of each critical care visit.**

Documentation

Regarding documentation, since critical care is a time-based service, CMS proposes to require practitioners to document in the medical record the total time that critical care services were provided by each reporting practitioner (not necessarily start and stop times). The documentation would also need to indicate that the services furnished to the patient, including any concurrent care by the practitioners, were medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Payment for the services of Teaching Physicians

As part of the E/M visit coding framework CMS finalized for CY 2021, practitioners can select the office/outpatient E/M visit level to bill based either on the total time personally spent by the reporting practitioner or MDM. CMS notes that stakeholders have asked how teaching physicians who involve residents in furnishing care should consider time spent by the resident in selecting the office/outpatient E/M visit level. In response, CMS proposes that when total time is used to determine the office/outpatient E/M visit level, only the time that the teaching physician was present can be included. CMS also notes that the teaching physician presence requirement can be met through audio/video real-time communications technology, only in residency training sites that are located outside of an MSA. **CMS seeks comment on whether time is an accurate indicator of the complexity of a visit when services are furnished under the primary care exception.**

Primary Care Exception Policy

Under the primary care exception, Medicare makes PFS payments in certain teaching hospital primary care centers for certain services of lower and midlevel complexity furnished by a resident without the physical presence of a teaching physician. CMS proposes that under the primary care exception, only MDM (rather than time) can be used to select the office/outpatient E/M visit level. CMS notes that it believes this is appropriate to prevent inappropriate coding that "reflects residents' inefficiencies rather than a measure of the time required to furnish the services". **CMS seeks feedback on this proposal.**

Billing for Physician Assistant Services

Although the payment amount for the services of physician assistants (PAs), nurse practitioners (NPs) and clinical nurse specialists (CNSs) is determined using the same methodology,[6] since the start of the PA benefit (with a limited narrow exception), payment for PA services must be made to the PA's employer and PAs are precluded from directly billing the Medicare program and receiving payment for their services, among other limitations. The CAA removed the requirement to make payment for PA services only to the PA's employer, effective January 1, 2022. As a result of this change, CMS notes PAs also may reassign their rights to payment for their services, and may choose to incorporate as a group comprised solely of practitioners in their specialty and bill the Medicare program in the same way that NPs and CNSs may do. In the Proposed Rule, CMS proposes various regulatory changes to implement the PA-related provisions of the CAA.

Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter as Certain Colorectal Cancer Screening Tests

Currently, the addition of any procedure beyond a planned colorectal cancer screening test (for which there is no coinsurance) results in the beneficiary having to pay coinsurance. The CAA included a provision to offer a special coinsurance rule for screening flexible igmoidoscopies and screening colonoscopies. The reduced coinsurance will be phased-in beginning January 1, 2022 and the phased-in Medicare payment percentages for colorectal cancer screening services and corresponding reduction in coinsurance are as follows:

- 80 percent payment for services furnished during CY 2022 (with coinsurance equal to 20 percent);
- 85 percent payment for services furnished during CY 2023 through CY 2026 (with coinsurance equal to 15 percent);
- 90 percent payment for services furnished during CY 2027 through CY 2029 (with coinsurance equal to 10 percent); and
- 100 percent payment for services furnished from CY 2030 onward (with coinsurance equal to zero percent).

Vaccine Administration Services

In the Proposed Rule, CMS seeks feedback on how the agency should update the payment rate for administration of preventive vaccines (i.e., influenza, pneumococcal, HPV and COVID-19) under Medicare Part B. CMS notes that over the past several years, stakeholders have expressed concerns about the reduction in Medicare Part B payment rates for the services to administer preventive vaccines. CMS seeks feedback, with specific questions listed in the Proposed Rule (pg. 304-306), regarding the development of an accurate and stable payment rate for administration of the preventive vaccines for physicians, NPPs, mass immunizers and certain other providers and suppliers.

Effective June 8, 2021, CMS announced a new add-on payment with a national rate of $35.50 when a COVID-19 vaccine is administered in the beneficiary's home and certain other circumstances are met. The agency has also provided additional information regarding the definition of "home" and other information related to billing. CMS continues to evaluate the needs related to COVID-19

[6] The Methodology is 80 percent of the lesser of the practitioner's actual charge or 85 percent of the amount that would be paid to a physician under the PFS.

vaccine administration, including at-home administration. **CMS seeks feedback regarding the definition of "home" and the types of clinical and non-clinical circumstances that make it difficult for a beneficiary to receive a COVID-19 vaccine outside the home. In addition, CMS requests feedback on whether it should keep these requirements during the PHE.** Also, CMS requests information about the circumstances in which health care providers, suppliers or others may need to vaccinate people at home rather than periodically in association with routine in-person visits. **CMS also seeks feedback regarding the costs associated with furnishing COVID-19 in the home and how these costs differ from traditional locations** (e.g., physician's office, mass immunization site).

Monoclonal Antibodies Used to Treat COVID-19

During the PHE, CMS decided to reimburse for certain COVID-10 treatments under the COVID-19 vaccine benefit with no beneficiary cost-sharing. When a treatment is provided, CMS makes a separate payment for the products (when not given to the provider or supplier free by the government) and for the service to administer them. However, as various changes occur (e.g., modifications to emergency use authorizations, new products entering the market), the federal government may not continue to provide products to providers and suppliers for free. **CMS seeks feedback on its approach to coverage and payment for COVID-19 monoclonal antibody products under the COVID-19 vaccine benefit.** CMS also indicates it is considering aligning payment and coverage for these products with the agency's approach for other monoclonal antibody products following the end of the PHE.

CMS is also interested in additional feedback on the resource costs of administering COVID-19 monoclonal antibody products, and the agency is interested in information on how the costs to furnish monoclonal antibodies for COVID-19 compare with infusions of other complex biologics.

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In the Proposed Rule, CMS provides several policies to support RHC and FQHCs and the agency also implements different sections of the CAA and American Rescue Plan Act (ARPA) that impact RHCs and FQHCs. Topics addressed in the Proposed Rule include mental health services furnished via telecommunications technologies for RHC and FQHCs, RHC payment limit per-visit, payment for attending physician services furnished by RHCs or FQHCs to hospital patients, concurrent billing for chronic care management services (CCM) and transitional care management (TCM) services for RHC and FQHCs and technical updates regarding COVID-19 vaccines furnished in RHCs and FQHCs. CMS also included a comment solicitation in the Proposed Rule (pg. 358-360) regarding tribal FQHC payments.

Requiring Certain Manufacturers to Report Drug Pricing Information for Part B and Determination of ASP for Certain Self-administered Drug Products

Requiring Certain Manufacturers to Report Drug Pricing Information for Part B

The CAA requires manufacturers without a Medicaid drug rebate agreement to report average sales price (ASP) information to CMS for calendar quarters beginning on January 1, 2022, for drugs or biologicals[7] payable under Medicare Part B and as further described in statute. With such data, CMS may calculate the ASP payment limit for a broader array of medications. In addition, the CAA requires the Office of the Inspector General (OIG) to submit a report on the accuracy of ASP

[7] As noted in the IFC, the CAA clarifies drugs would include items, services, supplies, and products that are payable under Medicare Part B as a drug or biological.

submissions to Congress by January 1, 2023. To implement these new manufacturer (including repackagers) reporting requirements (and potential civil monetary penalties), CMS provides various regulatory changes in the Proposed Rule and seeks stakeholder feedback broadly.

Determination of ASP for Certain Self-Administered Drug Products

The CAA requires the OIG to continue to conduct periodic studies to identify NDCs for drug or biological products that are identified to be self-administered for which payment is not be made under Part B. Based on these OIG studies, per the CAA, the Secretary shall, to the extent appropriate, set the payment as the lesser of the payment limit determined when the NDCs of self-administered drugs are included or the payment limit is determined after excluding the NDCs identified to be self-administered (the "lesser-of payment methodology").

CMS proposes that when OIG conducts a periodic study and informs CMS of the study (which is when the study becomes publicly available), then CMS will obtain the NDCs identified by the OIG study. To allow operational time for assessment, the application of the lesser-of methodology would be reflected beginning in the ASP pricing file two quarters following the OIG study publication. **CMS seeks comment on this proposal.**

When applying the lesser-of methodology, CMS proposes to make two calculations: (1) the ASP payment limit for the billing and payment code, excluding the NDCs that have been identified by the OIG study; and (2) the ASP payment limit for the billing and payment code, including such NDCs' ASPs and units sold. The calculation resulting in the lower payment limit would be used as the payment limit for the applicable billing and payment code for that quarter's ASP pricing files. CMS proposes to apply the lesser-of methodology to the billing and payment codes containing OIG-identified products each quarter when determining ASP payment limits. **CMS welcomes comment on these proposals.**

CMS proposes that the application of the lesser-of methodology would not apply if the drug or biological product is in short supply (i.e., if the drug and dosage form(s) represented by the billing and payment code are reported on FDA's drug shortage list) at the time that ASP limits are being finalized for the next quarter. CMS welcomes comments on these proposals.

Also, CMS indicates that while it does not anticipate substantial administrative costs, the OIG found that Medicare and its beneficiaries would have saved a combined $497 million on certolizumab pegol and abatacept over 2 years (2017—2018) if such a methodology had been in place.

Medicare Part B Drug Payment for Drugs Approved under Section 505(b)(2) of the Federal Food, Drug, & Cosmetic Act

Unlike reimbursement of sole source drugs which is based on a drug's ASP, multiple source small molecule drugs (e.g., all therapeutically equivalent brand name and generic drug products within the same HCPCS code) are reimbursed at ASP (based on the weighted average) plus 6 percent. According to CMS, for a subset of drugs approved by FDA under the 505(b)(2) pathway ("505(b)(2) drugs"), the distinction between multiple source drugs and single source drugs is less straightforward due to the different regulatory needs for approvals Unlike a generic drug product, 505(b)(2) drug products are not required to use the same FDA-approved labeling as the products relied upon for approval.

Due to CMS's concerns about price increases and spending on drugs approved through 505(b)(2) pathway, in the Proposed Rule, CMS proposes a framework for determining when section 505(b)(2) drug products without an FDA therapeutic equivalence rating to an existing drug product payable under Part B corresponds to an existing multiple source drug code for the purpose of payment

under Medicare Part B. **Notably, CMS is not proposing to adopt the framework at this time, but seeks comment on the framework to inform future policymaking.**

CMS solicits comment on the framework and how it aligns with the statutory definitions of single source and multiple source drugs and how the framework distinguishes situations in which a section 505(b)(2) drug is not described by an existing multiple source drug code. Also, CMS requests information on the potential impacts of the framework on Medicare beneficiaries, the government, and other stakeholders.

Appropriate Use Criteria for Advanced Diagnostic Imaging

The Protecting Access to Medicare Act (PAMA) directed CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services (e.g., computed tomography, positron emission tomography, nuclear medicine and magnetic resonance imaging). Under this program, ordering professionals are required to consult a qualified Clinical Decision Support Mechanism (CDSM), which is an electronic portal through which AUC is accessed. In addition, professionals identified as outlier ordering professionals must have a prior authorization requirement.

In response to the PHE and stakeholder feedback, CMS proposes a flexible effective date for AUC program claims processing edits and the payment penalty phase. Specifically, CMS proposes the effective date for penalties to be the later of January 1, 2023, or the January 1 that follows the declared end of the PHE for COVID-19. **CMS seeks stakeholder feedback regarding the start date of the payment penalty phase, including the readiness of practitioners, facilities and Electronic Health Record (EHR) and CDSM vendors.** CMS also reiterated that stakeholders may attest to a significant hardship under the AUC program (including as the AUC program processes into the payment penalty phase) due to extreme and uncontrollable circumstances surrounding the COVID-19 PHE, even when the PHE declaration is not in effect.

In the Proposed Rule, CMS also noted it will use future rulemaking to establish the methodology for the identification of outlier ordering professionals who would eventually be subject to a prior authorization process when ordering advanced diagnostic imaging services. In addition, the agency provides clarifications regarding modified orders and claims processing. For example, for institutional claims, CMS proposes to limit AUC program claims processing edits to apply only to type of bill 13x (hospital outpatient) as this claim type code encompasses the hospital outpatient department and the emergency department. For practitioner claims, CMS proposes to limit the edits to claims with place of service codes 11 (office), 15 (mobile unit), 19 (off campus outpatient hospital), 22 (on campus outpatient hospital), 23 (emergency room) and 24 (ASC). These place of service codes should encompass all applicable settings under the AUC program.

Removal of Select National Coverage Determinations

CMS proposes to remove two National Coverage Determinations (NCDs) (Enteral and Parenteral Nutritional Therapy - 180.2 and Positron Emission Tomography (PET) Scans – 220.6) and seeks comments on these proposals. For the NCDs for enteral and parenteral nutrition and PET scans, CMS provides in the Proposed Rule that it believes allowing local contractor discretion to make a coverage decision better services the needs of Medicare beneficiaries.

Pulmonary Rehabilitation, Cardiac Rehabilitation, and Intensive Cardiac Rehabilitation

CMS proposes revisions to the conditions for coverage for pulmonary rehabilitation (PR) program and the cardiac rehabilitation (CR) /intensive cardiac rehabilitation (ICR) programs. CMS proposes

changes to the regulatory text for the both the PR and CR/ICR programs to establish consistency in terminology, definitions and requirements in effort to provide more clarity.

In addition, CMS proposes to expand the PR program to include more covered conditions. Currently, regulations specify that PR is a physician-supervised program for COPD and certain other chronic respiratory diseases. CMS proposes to cover PR for Medicare beneficiaries who have been diagnosed with severe manifestations of COVID-19, defined as requiring hospitalization in the ICU or otherwise, and who experience continuing symptomatology, including respiratory dysfunction, for at least 4 weeks post discharge. **CMS is soliciting comments regarding the appropriateness of the coverage criteria for PR for beneficiaries diagnosed with COVID-19, including both the characteristics of the patients for whom PR is covered and the timing of their symptoms.**

Clinical Laboratory Fee Schedule: Laboratory Specimen Collection and Travel Allowance for Clinical Diagnostic Laboratory Tests and Use of Electronic Travel Logs

CMS restated its ongoing belief that the laboratory specimen collection fees for COVID-19 clinical diagnostic laboratory tests (CDLTs) established during the PHE should conclude at the termination of the PHE. Despite CMS's perspective regarding such laboratory specimen collection fees, **the agency seeks broad comment on its policies for specimen collection fees and the travel allowance as it considers updating these policies in the future. In addition, CMS seeks additional input on what additional resources might be needed for specimen collection for COVID-19 CDLTs and other tests after the PHE ends.**

In addition, in the Proposed Rule, CMS announced electronic logs (as opposed to paper-only) as a permanent option for laboratories to submit to Medicare Part B Medicare Administrative Contractors (MACs). CMS notes it will provide guidance in future instructions via forthcoming Change Requests and other materials such as MLN Matters® articles. Also, the agency clarified that laboratories will need to be able to produce electronic logs in a form and manner that can be shared with MACs, and should continue to consult with their local MACs regarding the format and process for ongoing submission of this information.

Medicare Provider and Supplier Enrollment

In the Proposed Rule, CMS indicates the overarching purposes of the Medicare enrollment process is to help confirm that Medicare providers and suppliers meet all federal and state requirements and to help with the oversight efforts. CMS proposes several changes to existing provider enrollment regulations. Specifically, CMS proposes to expand the categories of parties within the purview of the OIG's denial and revocation provisions. In addition, CMS proposes to deny or revoke a provider's enrollment if the provider surrenders his or her DEA certificate in response to an order to show cause. Also, the agency provides technical regulatory changes so that the agency can be more flexible in their decision to revoke a provider's or supplier's enrollment based on a pattern of submitting claims that fail to meet Medicare requirements.

The Proposed Rule also creates specific rebuttal rights when a provider's or supplier's billing privileges are deactivated and aims to modernize enrollment policies for independent diagnostic testing facilities (IDTFs).

Lastly, regarding provider/supplier medical review requirements, CMS proposes to add new regulatory language regarding prepayment and post-payment review and CMS's contractors' authority to deny a claim should a provider or supplier fail to convey the additional documentation in response to a request.

Updates to the Physician Self-Referral Regulations

Section 1877 of the Social Security Act, also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. CMS provides various policies to update the self-referral regulations in the Proposed Rule. Notably, CMS proposes to include as a potential indirect compensation arrangement any unbroken chain of financial relationships in which the compensation arrangement (e.g., service-based compensation for the rental of office space or equipment) closest to the physician (or immediate family member of the physician) involves compensation for anything other than services that he or she personally performs. CMS also provides a definition of "unit" for purposes of determining whether the unbroken chain of financial relationships constitutes an indirect compensation arrangement. **CMS seeks comment on these proposals and whether additional guidance is needed to determine whether an indirect compensation arrangement exists.**

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

In the CY 2021 PFS final rule CMS provided a January 1, 2022, compliance date for electronic prescribing of controlled substance (ECPS) for a covered Part D drug under a prescription drug plan or an MA-PD plan. In the Proposed Rule, CMS provides various reasons why implementation has been challenging and proposes to change the EPCS compliance date from January 1, 2022 to January 1, 2023.

In addition, CMS proposes that for prescribers to be considered compliant with the EPCS mandate, they must prescribe at least 70 percent of their Part D controlled substance prescriptions electronically. CMS would conduct this calculation by examining prescription drug event (PDE) data at the end of the calendar year and dividing the number of Part D controlled substances that the prescriber e-prescribed by the total number of Part D controlled substance prescriptions that the prescriber prescribed. **CMS seeks comment on this method and the proposal.**

In the Proposed Rule, CMS also details various exceptions to the e-prescribing requirement (e.g., prescriptions issued when the prescriber and dispensing pharmacy are the same entity, cases where prescribers issue only a small number of Part D prescriptions and in cases of recognized emergencies and extraordinary exceptions). In the Proposed Rule, CMS outlines the circumstances by which an exception would be triggered or when an exception would need to be granted. CMS also noted it will include more information about exceptions in subsequent rulemaking.

Regarding compliance actions, CMS may send letters to prescribers that CMS believes are violating the EPCS requirement during CY 2023. **CMS seeks comment on this proposal, including what type of compliance action may be appropriate after the initial period described above, including whether any penalties should be phased in over time.**

Open Payments

The Open Payments program is a statutorily-mandated program that requires manufacturers of covered drugs, devices, biologicals, or medical supplies (referred to as "applicable manufacturers"), as well as applicable group purchasing organizations (GPOs), to annually submit information for the

preceding calendar year about certain payments or other transfers of value made to “covered recipients” Covered recipients is currently defined as physicians, teaching hospitals, physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), certified registered nurse anesthetists (CRNAs) & anesthesiologist assistants (AAs), and certified nurse-midwives (CNMs). Payments or other transfers of value that must be reported include research-related payments, honoraria, gifts, travel expenses, meals, grants and other compensation.

In the Proposed Rule, CMS aims to clarify existing Open Payments requirements and add provisions to improve the quality of the data. Generally, CMS proposes the following revisions effective for data collection beginning in CY 2023 and reporting in CY 2024:

- Adding a mandatory payment context field for records to teaching hospitals;
- Adding the option to recertify annually even when no records are being reported;
- Disallowing record deletions without a substantiated reason;
- Updating the definition of ownership and investment interest;
- Adding a definition for a physician-owned distributorship as a subset of applicable manufacturers and GPOs;
- Requiring reporting entities to disclose relationships they have with other companies for the purposes of transparent reporting;
- Disallowing publications delays for general payment records;
- Clarifying the exception for short-term loans applies for 90 total days in a calendar year, regardless of whether the 90 days were consecutive; and
- Removing the option to submit and attest to general payment records with an “Ownership” Nature of Payment category.

Updates to the Quality Payment Program

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Quality Payment Program (QPP) for eligible clinicians. Under the QPP, Merit-based Incentive Payment System (MIPS) eligible clinicians can participate via one of two tracks – the MIPS (reporting available via traditional MIPS or MIPS Value Pathways (MVPs)) or the Advanced Alternative Payment Models (Advanced APMs). Eligible clinicians participating in MIPS are subject to a MIPS payment adjustment based on their relative performance in four performance categories: Cost, Quality, Improvement Activities and Promoting Interoperability (PI). Alternatively, eligible clinicians electing to participate in the Advanced APM pathway automatically receive a bonus payment once certain qualifications for the track are met.

Generally, the Proposed Rule sets forth changes to the QPP starting January 1, 2022, except as otherwise noted for specific provisions. The Proposed Rule provides additional detail regarding the implementation of MVPs and moves towards sunsetting traditional MIPS, however, a proposal to sunset traditional MIPS would be made in future rulemaking. In conjunction with the Proposed Rule’s release, CMS also provided a Quality Payment Program Fact Sheet.

MIPS Value Pathways (MVPs)

In the CY 2020 PFS final rule, CMS establishes MVPs which are a subset of measures and activities that are relevant to a specialty, medical condition or specific population, and can be used to meet MIPS reporting requirements. Consistent between MVPs is a foundation of PI performance requirements and population health claims-based measures. In the Proposed Rule, CMS proposes seven new MVPs: Rheumatology, Stroke Care and Prevention, Heart Disease, Chronic Disease Management, Emergency Medicine, Lower Extremity Joint Repair and Anesthesia. Each MVP would have different measures and activities in the quality, improvement activities and cost performance categories but each MVP would have the same foundational layer (population health measures and PI performance category) as. provided in the below table.

Quality Performance Category*	Improvements Activities Performance Category*	Cost Performance Category
An MVP Participant selects: - Four quality measures, one must be an outcome measure (or a high priority measure if an outcome is not available or applicable). - As applicable, an administrative claims measure, that is outcome-based, may be selected at the time of MVP registration to meet the outcome measure requirement.	An MVP Participant selects: - Two medium weighted improvement activities; OR - One high weighted improvement activity OR - Participates in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice.	An MVP Participant, is scored on the cost measures that are included in the MVP that they select and report.
Foundational Layer (MVP agnostic)		
Population Health Measures*: An MVP Participant selects 1 population health measure, at the time of MVP registration, to be scored on. The results are added to the quality performance category score.		
Promoting Interoperability (PI) Performance Category: An MVP Participant is required to meet the Promoting Interoperability performance category requirements (more information below).		

*Indicates MVP Participant may select measures and/or improvement activities.

MVP Participant

In the Proposed Rule, CMS seeks to clarify who can participate in MIPS through MVPs. Specifically, CMS proposes that the term MVP Participant means: an individual MIPS eligible clinician, multispecialty group, single specialty group, subgroup or APM Entity that is assessed on an MVP for all MIPS performance categories. However, for the CY 2025 MIPS performance period/2027 MIPS payment year and future years, the definition of MVP Participant would narrow to exclude multispecialty groups. CMS would exclude multispecialty groups to account for the transition to requiring multispecialty groups to form subgroups if they want to report MVPs. **CMS seeks comment on whether opt-in participants, voluntary participants and virtual groups should be allowed to report MVPs as MVP Participants in future years.**

Subgroups

In the Proposed Rule, CMS aims to establish subgroup reporting as an option for MVP Participants and those who chose to report the APM Performance Pathway (APP).[8] A goal of subgroup reporting is to allow for more granular reporting from the MIPS program. CMS proposes to define a subgroup as a subset of a group which contains at least one MIPS eligible clinician and is identified by a combination of the group Taxpayer Identification Number (TIN), the subgroup identifier and each eligible clinician's National Provider Identifier.

Groups would identify their affiliated subgroups, and those subgroups would submit data on the MVPs. Each MIPS eligible clinician in the subgroup would receive a final score based on the subgroup's combined performance. **CMS requests feedback on the structure of subgroups, and**

[8] In the Proposed Rule, CMS proposes definitions for subgroup reporting, single specialty group, and special status designation; subgroup eligibility requirements; and application of low-volume threshold and special status designations for subgroups. CMS also includes a request for information on the future direction of subgroup reporting.

how they are assessed and scored in the future as clinician gain familiarity with the program, more MVPs are developed, and technological advancements allow for low-burden reporting.

Notably, subgroups can be voluntarily formed for the CY 2023-CY 2024 MIPS Performance period/ 2025 and 2026 MIPS payment years. The below table provides information regarding CMS's proposed implementation timeline for subgroups.

MVP Implementation Timeline

In the Proposed Rule, based on stakeholder requests for gradual implementation, CMS proposes delaying the implementation and availability of the proposed MVPs by one year, that is, until the CY 2023 MIPS performance period/2025 MIPS payment year. Generally, CMS proposes the registration period would begin on April 1 until November 30 of the applicable performance period. Table 35 (pg. 791) of the Proposed Rule outlines the proposed registration process for MVP and subgroup elections beginning with the CY 2023 MIPS performance period. **CMS requests comment on these proposals.**

The below table outlines CMS's thinking for the MVP Implementation Timeline and the Subgroup Implementation Timeline. **CMS seeks feedback regarding each timeline, particularly the future consideration noted in the below table.**

MVP Implementation Timeline	
Proposal:	
CY 2023 MIPS Performance period	An initial set of MVPs are available for reporting; MVP reporting is voluntary.
For Future Consideration:	
CY 2024-CY 2027 MIPS Performance Periods	The existing MVP portfolio would be gradually updated to include newly developed MVPs that are available for reporting. MVP reporting is voluntary.
End of CY 2027 MIPS Performance Period and Corresponding Data Submission Period	Considering sunset of traditional MIPS.
CY 2028 MIPS Performance Period, and Future Years	Considering mandatory MVP reporting.
Subgroup Implementation Timeline*	
CY 2023-CY 2024 MIPS Performance Period/ 2025 and 2026 MIPS Payment Years	Groups may voluntarily form subgroups to report MVPs. Public reporting on Care Compare of subgroup performance information beginning with the CY 2024 MIPS performance period/2026 MIPS payment year.
CY 2025 MIPS Performance Period/2027 MIPS Payment Year, and Future Years	Multispecialty groups would be required to form subgroups to report MVPs

**CMS is not proposing mandatory MVP reporting but does request public comment on the agency's future timeline.*

MVP Scoring

For scoring in MVPs, CMS generally proposes to align scoring policies (e.g., general performance category weights, complex patient bonus), with finalized policies in traditional MIPS with some exceptions. For example, for the MVP improvement activities performance category, CMS proposes assigning 20 points for each medium-weight improvement activity and 40 points for each high-weight improvement activity to align with CMS's proposed MVP reporting requirements. CMS believes that this would help to incentivize clinicians to report on MVPs versus traditional MIPS since fewer submissions are required to receive a full score. In the Proposed Rule, CMS also details

scoring for subgroups, circumstances in which CMS would reweight performance categories within an MVP and application of the complex patient bonus to MVPs.

CMS also proposes using enhanced performance feedback in MVPs. According to CMS, a goal of enhanced performance feedback would be to compare similar clinicians to one another. Beginning with the CY 2023 performance period, CMS proposes to include comparative performance feedback of clinicians who report on the same MVP within the annual performance feedback it provides for MVP Participants. **Also, CMS seeks stakeholder feedback to get a better understanding of what is considered "actionable" feedback. CMS asks whether actionable feedback could include CMS identifying in the annual performance feedback areas of improvement based on how a clinician scores on a measure. CMS also asks whether there is an unintended burden on stakeholders associated with receiving actionable feedback.**

APM Performance Pathway (APP)

In the CY 2021 PFS Final Rule, CMS finalized the APP[9], including measure sets and weights, as it effectively replaces the MIPS APM scoring standard. The APP is meant to provide a predictable and consistent reporting option and is available for reporting by any submitter type, except virtual groups. Table 40 (pg. 812) in the proposed Rule outlines measures included in the Proposed APP measure set. **CMS seeks comment on the proposed measures.**

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

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

Traditional MIPS

In accordance with statutory requirements, for the 2022 performance period CMS provides the following performance category weights: Quality (30 percent, a 10 percent decrease from CY 2021); Cost (30 percent, a 10 percent increase from CY 2021); Improvement Activities (15 percent, no change from CY 2021); and Promoting Interoperability (25 percent, no change from CY 2021).

For the CY 2022 performance period/2024 MIPS payment year, CMS proposes a performance threshold of 75 points and 89 points for the exceptional performance threshold. Table 59 (pg. 1013) of the Proposed Rule compares the 2023 and 2024 payment years' point systems and associated adjustments between the finalized 2023 MIPS payment year and proposed 2024 MIPS payment year.

In the Proposed Rule, CMS proposes amending the definition of "MIPS eligible clinician" to include clinical social workers and certified nurse midwives.

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

Quality Performance Category

For the 2022 performance period, CMS proposes to reduce the number of quality measures from 206 to 195. In addition, the agency proposes substantive changes to 84 existing MIPS quality measures, changes (including measure removal) to specialty sets and the addition of five quality measures, including two new administrative claims measures. CMS also shares its intent to propose the COVID-19 Vaccination by Clinicians measure in future rulemaking and requests information on this measure as described below.

For quality benchmarks, due to CMS's extreme and uncontrollable circumstances policies in effect for CY 2020, the agency proposes to use performance period benchmarks for the 2022 period. It is important to note, CMS is also considering utilizing the historic benchmarks from the 2021 MIPS performance period for the CY 2022 performance period/2024 MIPS payment year. **CMS seeks feedback on alternatives to performance period benchmarks.**

Also, like the APP web interface policy, CMS similarly proposes to extend the CMS Web Interface quality reporting option for the 2022 performance period.

To meet data completeness criteria, performance data must be reported for a specific percentage of the denominator for eligible encounters. Due to the COVID-19 PHE, CMS proposes to maintain the data completeness criteria of at least 70 percent for the 2022 MIPS performance period (2024 MIPS payment year). For the 2023 MIPS performance period (2025 MIPS payment year), CMS proposes to increase the data completeness criteria by 10 percent to at least 80 percent.

Cost Performance Category

CMS proposes to add 5 new episode-based measures (see Table 41, pg. 849) to the cost performance category beginning with the 2022 performance period. The proposed measure specifications are available on the CMS website. In addition, CMS proposes to update the operational list of care episode and patient condition groups and costs. The proposed rule also includes a new process for stakeholders to develop cost measures for MIPS and criteria for determining whether a cost measure changes is considered substantive starting with the 2022 MIPS performance period.

CMS indicates that due to the PHE, the scores for cost measures cannot be reliably calculated. As such, CMS will assign a weight of 0% to the cost performance category for the PY 2020 MIPS /CY 2022 payment year. **CMS seeks feedback on additional external factors beyond clinical control that may limit the agency's ability to reliably calculate cost measure scores in the future.**

Improvement Activities Performance Category

CMS proposes to add 7 new improvement activities, modify 15 existing improvement activities and remove 6 previously adopted improvement activities for the CY 2022 performance period and future years. CMS also proposes changes to adopted improvement activities, including "Drug Cost Transparency" to require use of real-time benefit tools and to extend the COVID-19 Clinical Data Reporting with or without Clinical Trial improvement activity for CY 2022 performance period and future years. In addition, CMS proposes changes to the criteria for nominating a new improvement activity.

PI Performance Category

In the Proposed Rule, CMS provides numerous changes the PI Performance Category, primarily regarding measures.

Regarding the Query of Prescription Drug Monitoring Program (PDMP) measure (under the Electronic Prescribing objective), CMS proposes that the PDMP measure will remain optional and

be worth 10 bonus points for the CY 2022 performance period/2024 MIPS payment year. **CMS seeks stakeholder comment on plans for requiring the Query of PDMP measure in the PI performance category in the near future, including what, if any, changes to the Query of PDMP measure would be necessary to accommodate other technical approaches that may be implemented in the future (e.g., exchange of information with a PDMP or with multiple PDMPs using HL7® FHIR®).**

CMS proposes changes to the Provide Patients Electronic Access to Their Health Information measure (under the Provider to Patient Exchange Objective). Since this measure currently does not specify how long MIPS eligible clinicians are required to make patient data available, CMS proposes to modify the measure to require MIPS eligible clinicians to ensure patient health information remains available indefinitely, as well as an encounter start date of January 1, 2016. **CMS seeks comment on this proposal**. Also under the Protect Patient Health Information objective, CMS proposes to add a new SAFER Guides[10] measure the beginning with the CY 2022 performance period/2024 MIPS payment year. For this measure, CMS proposes that a MIPS eligible clinician must attest to having conducted an annual self-assessment using the High Priority Practices Guide at any point during the calendar year in which the performance period occurs.

To support the comprehensive exchange needed for future public health responses, CMS proposes to require reporting for two of the measures associated with the Public Health and Clinical Data Exchange Objective, beginning with the performance period in CY 2022. Those two measures are: Immunization Registry Reporting and Electronic Case Reporting. For scoring, a MIPS eligible clinician would receive 10 points if they report a "yes" to both of those two required measures. CMS proposes to retain the other measures (Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting) but to make them optional and available for 5 bonus points beginning with the performance period in CY 2022. Reporting on more than one of these optional measures would not lead to additional bonus points.

Regarding attestation requirements for the PI performance category, CMS proposes to only require one statement for attestation.

CMS also proposes changes to the points available in the PI Performance category. For scoring, CMS restates that PDMP measure would be worth 10 bonus points and that submission of a "yes" for the Public Health Registry Reporting measure or the Clinical Data Registry Reporting measure or the Syndromic Surveillance Reporting measure would be worth 5 bonus points.

Lastly, CMS notes it will apply automatic reweighting to clinical social workers and small practices beginning with the CY 2022 performance period.

Additional Final Scoring Policies

For the CY 2022 performance period/2024 MIPS payment year, CMS intends to continue to build on the scoring methodology finalized for prior years. Table 51 (pg. 994) provides the performance category redistribution policies finalized in the CY 2021 PFS Final Rule for the CY 2022 Performance Period/2024 MIPS Payment Year and Proposed for Future MIPS Performance Periods/MIPS Payment Years. In the Proposed Rule, CMS provides additional information on redistributing performance category weight for small practices.

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[10] ONC developed and released the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) in 2014, and later updated them in 2016. This series of nine user guides support the ability of health care providers to address EHR safety.

Beginning with the 2022 MIPS performance period, CMS proposes to update the complex patient bonus in several ways, including limiting the bonus to clinicians who have a median or higher value for at least one of the two risk indicators (HCC and dual proportion) to better target clinicians who have a higher share of socially and/or medically complex patients and to cap the bonus at 10 points. Notably, in response to COVID-19 PHE, for the 2021 performance period, CMS proposes to double the complex patient bonus and that the doubled numerical value (subject to the 10-point cap) would be added to the final score.

Three Requests for Information Related to Promoting Interoperability

CMS provides three requests for information (RFIs) related to MIPS in the Proposed Rule.

The first RFI seeks comments on the agency's goal of aligning additional PI performance category objectives with approaches utilizing HL7® FHIR® standard Release 4-based API functionality (or the appropriately evolved standard), specifically targeting the Health Information Exchange as well as the Public Health and Clinical Data Exchange objectives. A complete list of questions is available in the Proposed Rule (pg. 927-928).

The second RFI asks for comments on changes to the PI performance category and related efforts which could better target patient access outcomes related to use of patient portals or third-party application(s). A complete list of questions is available in the Proposed Rule (pg. 929).

The third RFI seeks comments on changes CMS can make that will better support the goals of the OpenNotes movement to ensure that clinical notes are widely available to patients. A complete list of questions is available in the Proposed Rule (pg. 930).

Request for Information Regarding the COVID-19 Vaccination by Clinicians Measure

In response to the COVID-19 PHE, CMS began the development of the COVID-19 Vaccination by Clinicians measure for MIPS. The measure aims to assess the percentage of patients aged 18 years and older seen for a visit during the measurement period who have completed or reported having completed a COVID-19 vaccination series. The measure would be reported by MIPS eligible clinicians as a MIPS CQM. CMS seeks public comment on the draft COVID-19 Vaccination by Clinicians measure specifications, (available on the Quality Payment Program website). Among other questions, CMS asks stakeholders whether the measure should assess whether or not patients completed a COVID-19 vaccination series.

Advanced APMs

Any eligible clinicians that participate in an Advance APM and satisfy Qualifying APM Participant (QP) thresholds are excluded from the MIPS reporting requirements and payment adjustments. The CAA included different provisions related to QP thresholds which CMS provides in Table 63 (pg. 1061) of the Proposed Rule.

Medicare Shared Savings Program

The Medicare Shared Savings Program (MSSP) serves as a mechanism for eligible groups of providers and suppliers that participate in an Accountable Care Organization (ACO) to continue to receive traditional Medicare FFS payments and a shared savings payment if the ACO meets specified quality and savings requirements. CMS proposes numerous changes to the MSSP and provides an additional fact sheet that includes information on the MSSP changes provided in the Proposed Rule.

In the CY 2021 PFS Final Rule, CMS finalized the APP[11] where ACOs would report clinical quality measures using all-payer data rather than the CMS Web Interface starting in PY 2022. In the Proposed Rule, CMS proposes to extend reporting via CMS Web Interface. Specifically, for PY 2022, ACOs would have the option to report either 10 CMS Web Interface measures or the three all-payer eCQMs/MIPS CQMs. Under the APP, all ACOs are also to administer the CAHPS for MIPS Survey and be scored on two administrative claims-based measures. Notably, for PY 2023, CMS proposes that the CMS Web Interface would be a collection type under the APP only for Shared Savings Program ACOs. **CMS seeks comment on whether it should further extend the CMS Web Interface collection type.** For PY 2023, unlike PY 2022, ACOs electing the Web Interface option would need to report at least one all-payer eCQM/MIPS CQM. **CMS seeks comment on these proposed updates to the reporting requirements for PY 2022 and subsequent years.**

The quality performance standard is the minimum performance level ACOs must achieve to be eligible to share in any savings earned, avoid maximum shared losses under certain payment tracks and avoid quality-related compliance actions. In the CY 2021 PFS final rule, CMS finalized a gradual phase-in of a revised quality performance standard.[12] Due in part to the PHE, for PY 2023, CMS proposes to freeze the Shared Savings Program quality performance standard at the 30th percentile across all MIPS Quality performance category scores (excluding entities/providers eligible for facility-based scoring). Table 24 (pg. 452) of the Proposed Rule provides an overview of the proposed shared savings program ACO quality reporting requirements and the shared savings program ACO quality performance standard for PY 2021-2024.

In the Proposed Rule, CMS also proposes to expand the definition of primary care services (e.g., to include codes provided in the Proposed Rule and prolonged office or other E/M services; certain telephone E/M codes) used in beneficiary assignment in the Shared Savings Program. CMS also proposes to modify the approach to calculating repayment mechanism amounts and ease Shared Savings Program application burdens.

The agency also provides comment solicitations related to MSSP on the following topics: Addressing Health Disparities and Promoting Health Equity (e.g., how ACOs can improve the quality of care provided to certain communities, while addressing the disparities that currently exist in healthcare; how CMS can encourage health care providers serving vulnerable populations to participate in ACOs); Use of Regional FFS Expenditures in Establishing, Adjusting, Updating, and Resetting the ACO's Historical Benchmark; Request for Comment on the Shared Savings Program's Risk Adjustment Methodology; Comment Solicitation on Feasibility of TIN Level Reporting and Sampling for eCQMs/MIPS CQMs; and Comment Solicitation for Reporting Options for Specialist Providers within an ACO.

Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs – Request for Information

In the Proposed Rule, CMS notes its goal to move fully to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. As a result, and consistent with CMS's approach in other annual rules, the agency provides a request for information to inform the

[11] The APP is a MIPS reporting and scoring pathway for MIPS eligible clinicians who are also participants in MIPS APMs.
[12] An ACO would meet the revised quality performance standard if: for PYs 2021 and 2022, the ACO achieves a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring; and for PY 2023 and subsequent performance years, the ACO achieves a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.

agency's transition to digital quality measurement. Any updates to specific program requirements related to providing data for quality measurement and reporting provisions would be addressed through future rulemaking, as necessary.

To advance digital quality measurement, CMS identifies four potential action in four areas it is considering:

1. Leverage and advance standards for digital data and obtain all EHR data required for quality measures via provider FHIR-based APIs;
2. Redesign CMS quality measure to be self-contained tools;
3. Better support data aggregation; and
4. Work to align measure requirements across reporting programs, other Federal programs and agencies, and the private sector, where appropriate.

A complete list of questions in the RFI is available in the Proposed Rule (pg. 691-693).

Closing the Health Equity Gap in CMS Clinician Quality Programs – Request for Information

In the Proposed Rule, CMS indicates its intent to revise several CMS programs to make reporting of health disparities based on social risk factor and race and ethnicity more comprehensive and actionable for hospitals, providers and patients. As such, CMS is considering expanding their efforts to provide stratified data for additional social risk factors and measures, optimizing the ease-of-use of the results, enhancing public transparency of equity results and building towards provider accountability for health equity. **CMS seeks comment on future potential stratification of quality measure results by race and ethnicity and improving demographic data collection.** CMS is particularly interested in the steps the agency can take within the MIPS program to further bridge the equity gap.

What's Next?

CMS typically publishes the final PFS/QPP regulation in early November and the comment period closes on September 13, 2021. Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this proposed rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. Please direct your feedback to Jenna Stern, Sr. Regulatory Affairs and Public Policy Director in Vizient's Washington, D.C. office.