

CY 2022 Physician Fee Schedule Proposed Rule Summary

On July 13, the Centers for Medicare & Medicaid Services (CMS) released the Medicare Physician Fee Schedule (MPFS) proposed rule for CY 2022. This rule updates payment policies and payment rates for Part B services furnished under the MPFS, as well as makes changes to the Quality Payment Program (QPP). The rule in its entirety and the addenda, including Addendum B, which lists the proposed RVUs for each CPT code can be found here.

The following summarizes the major policies in the proposal. Note that the page numbers listed in this document refer to the display copy of the proposed rule.

Conversion Factor and Specialty Impact (p. 1177)

The proposed conversion factor for 2022 is \$33.5848, a decrease of \$1.31 from the 2021 conversion factor of \$34.8931, a decrease of 3.75 percent. This reduction is the result of the expiration of the 3.75 percent increase Congress included in the Consolidated Appropriations Act, 2021 as well as the fact there is no statutory increase to the conversion factor for 2022. Table 123 provides a summary of the impact of the changes, excluding the conversion factor decrease, in the proposed rule by specialty. The changes in the rule are budget-neutral in the aggregate, which explains why the impact for all physicians is shown as zero.

Based on an analysis conducted by the American Medical Association, the proposed changes in the rule, including the conversion factor decrease, would result in a -2.2 percent decrease for endocrinology. Note that the changes to practice expense covered in this summary result in significant decreases for some procedures commonly performed by endocrinologists. The overall impact of this proposed rule on an individual provider's reimbursement will depend upon their case mix.

Practice Expense Clinical Labor Pricing Update (p. 48)

CMS began updating supply and equipment prices used for direct practice expense (PE) inputs in 2019 and 2022 will be the final year of the transition to these new inputs based on work StrategyGen's market research study. When this work started, the agency did not propose to update the clinical labor pricing which has remained unchanged since CY 2002. Stakeholders have suggested certain wage rates are inadequate because they do not reflect current wage information and updating supply and equipment pricing without updating clinical labor could create distortions in direct PE allocation in a budget neutral system.

In this rule, CMS is proposing to update the clinical labor pricing using the most current Bureau of Labor Statistics (BLS) data in CY 2022 in conjunction with the final year of the supply and equipment pricing update. Table 5 includes the proposed clinical labor pricing updates. The agency is requesting comments on this proposal and is particularly interested in additional wage data for clinical labor types for which there was no direct BLS wage data. Table 6 shows the impact of this proposed change by specialty. CMS estimated the specialty-specific impacts of this change as well as those if the policy were to be phased in over four years (which can be found in Table 135) with endocrinology seeing a 2 percent increase in reimbursement as a result if implemented all at once and a 1 percent increase if it is phased in over four years.



These specialty impacts are largely driven by the share that labor costs represent of the direct PE inputs for each specialty such that specialties with substantially higher or lower than average share of direct costs attributable labor will experience the most significant changes. CMS is considering a 4-year transition to implement the clinical labor pricing update to smooth out the increases and decreases but recognizes this would mean the agency will continue to rely on outdated data for clinical labor pricing.

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 (p. 78) Proposed Changes to the Medicare Telehealth Services List (p. 79)

CMS rejected requests to add the following services to the telehealth list on a permanent basis:

- CPT code 51741 Complex uroflowmetry (e.g., calibrated electronic equipment)
- CPT code 90901 Biofeedback by any modality
- CPT code 90912 Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient
- CPT code 90913 Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)

The full list of services is available in Table 8 of the rule.

Revised Timeframe for Consideration of Services Added to the Telehealth List on a Temporary Basis (p. 90)

CMS is considering adding additional services to the Medicare telehealth services list using Category 3 which was established in rulemaking last year to add services on a temporary basis following the end of the COVID-19 public health emergency. These are services likely to have a clinical benefit when furnished via telehealth, but there is not yet sufficient evidence for the agency to consider adding them to the telehealth list on a permanent basis. The agency is proposing to revise the timeframe for services added to the list on a temporary basis and allow them to remain until the end of CY 2023 as this will allow for more time to collect utilization data and provide stakeholders with time to have them considered for permanent addition to the telehealth list under the agency's regular process.

The agency includes a separate list of services added to the telehealth list on an interim basis in response to the COVID-19 public health emergency, but not on a Category 3 basis (Table 11); these services will be removed when the public health emergency expires and include hospital inpatient services (CPT codes 99221-3), observation care services (CPT codes 99218-20, 99234-6), and telephone visit services (CPT codes 99441-3).

Implementation of Provisions of the Consolidated Appropriations Act, 2021 (CAA) (p. 100)

The Consolidated Appropriations Act, 2020 ("the Act") included a provision to broaden the scope of services for which the telehealth originating site and geographic restrictions will not apply-- services furnished for the purpose of diagnosis, evaluation, or treatment of a mental health disorder—effective at the conclusion of the COVID-19 public health emergency. The Act does require the provider to see the



patient in-person within 6 months or delivering these services via telehealth to the patient. For patients being treated or diagnosed with a substance use disorder or co-occurring mental health disorder, this in-person requirement does not apply.

Payment for Medicare Telehealth Services Furnished Using Audio-Only Communication Technology (p. 107)

CMS remains concerned that the use of audio-only communication for Medicare telehealth services could lead to inappropriate overutilization outside of the public health emergency and believes video visualization of the patient generally is necessary to fulfill the full scope of service elements of the codes included on the Medicare telehealth list. The agency is reassessing this position given the utilization of these services during the public health emergency; they observed audio-only E/M visits have been some of the most commonly performed telehealth services and most beneficiaries receiving these services were being treated for a mental health condition. Given the shortage of mental health professionals and limited broadband access in some areas, the agency will allow mental health services to be delivered to established patients using the audio-only modality when the originating site is their home. The Act removed the geographic restriction for Medicare telehealth services for the diagnosis, evaluation, or treatment of a mental health disorder and adds the patient's home as a permissible originating site for these services, making this possible. The agency is proposing to adopt a similar ongoing requirement that an in-person item or service must be furnished within 6 months of such a mental health telehealth service and is limiting the use of audio-only to services delivered by practitioners who have the capacity to furnish two-way, audio/video telehealth services but are providing the mental health services via audio-only communication technology in an instance where the beneficiary is unable to use, does not wish to use, or does not have access to two-way, audio/video technology. The agency is creating a service-level modifier to identify these services to monitor utilization and address program integrity concerns.

Other Non-Face-to-Face Services Involving Communications Technology under the PFS Expiration of PHE Flexibilities for Direct Supervision Requirements (p. 112)

CMS is soliciting information on whether the public health emergency-related flexibilities related to direct supervision should be made permanent by revising the definition of "direct supervision" to include immediate availability through the virtual presence of the supervising physician or practitioner using real-time, interactive audio/video communications technology without limitation. Specifically, the agency seeks comment on 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 public health emergency, and whether physicians and practitioners anticipate relying on this flexibility after the public health emergency concludes. CMS also seeks comment on the possibility of permanently allowing immediate availability for direct supervision through virtual presence using real-time audio/video technology for only a subset of services, as it may be inappropriate to allow direct supervision without physical presence for some services, due to potential concerns over patient safety.

Virtual Check-in - G2252

In the CY 2021 rule, CMS adopted a longer virtual check-in HCPCS code G2252 (Brief communication technology-based service, e.g., 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) on a temporary basis. The agency is proposing to permanently adopt his code and payment based on the support it has received.

Principal Care Management and Chronic Care Management (CPT codes 99490, 99439, 99491, 99X21, 99487, 99489, 99X22, 99X23, 99X24, and 99X25) (p. 196)

For CY 2022, the RUC resurveyed the CCM code family, including Complex Chronic Care Management (CCCM) and Principal Care Management (PCM), and added five new CPT codes: 99X21 (Chronic care management services each additional 30 minutes by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)), 99X22 (Principal care management services for a single high-risk disease first 30 minutes provided personally by a physician or other qualified health care professional, per calendar month), 99X23 (Principal care management services for a single high-risk disease each additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure), 99X24 (Principal care management services, for a single high-risk disease first 30 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month), and 99X25 (Principal care management services, for a single high-risk disease each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)).

The CCM/CCCM/PCM code family now includes five sets of codes, each set with a base code and an addon code. The sets vary by the degree of complexity of care (that is, CCM, CCCM, or PCM), who furnishes the care (that is, clinical staff or the physician or NPP), and the time allocated for the services. CMS is proposing to accept the work and PE values as recommended by the RUC as outlined in Table 12.

CMS is also interested in understanding the process employed to get beneficiary consent for these services and asks for comment on this issue, specifically on what levels of supervision are necessary to obtain beneficiary consent when furnishing CCM services and will consider such comments in future rulemaking.

Evaluation and Management (E/M) Visits (p. 241)

CMS is continuing to refine its existing E/M policies and is proposing policies regarding split (or shared) visits, critical care services, and teaching physician visits.

Split (or Shared) Visits (p. 241)

A split (or shared) visit refers to an E/M visit that is performed ("split" or "shared") by both a physician and a NPP who are in the same group. CMS needs to address whether and when a physician can bill for these visits because they are reimbursed at a higher rate than an NPP. In the office, physicians can bill for these services when the NPP's services are "incident to" the physician's professional services; however, the "incident to" rules do not apply in the facility setting. The agency sees the changes in the rule as distinguishing between split (or shared) visits and those services furnished incident to the professional services of a physician.

CMS is proposing the following changes:

• Definition of spit (or shared) visits: In the facility setting, a split (or shared) visit is one performed in part by both a physician and a NPP who are the same group where "incident to" billing is



prohibited and is furnished in accordance with applicable law and regulation, including conditions of coverage and payment, such that the E/M visit could be billed by either the physician or the NPP if it were furnished independently by only one of them in the facility setting.

- Physicians and NPPS can bill split (or shared) visits for both new and established patients and for critical care and certain SNF/NF E/M visits.
- Definition of "substantive portion": Only the physician or NPP who performs the substantive portion of the visit would bill for it, so the agency proposes "substantive portion" to mean more than half of the total time spent by the physician and NPP performing the visit.
- *Distinct time:* The distinct time spent by each physician or NPP furnishing a split (or shared) visit would be summed to determine the total time and who provided the substantive portion.
- Qualifying time: CMS is proposing a listing of activities that could count toward total time for determining substantive portion (for services other than for critical care) including:
 - Preparing to see the patient (for example, review of tests).
 - o Obtaining and/or reviewing separately obtained history.
 - o Performing a medically appropriate examination and/or evaluation.
 - o Counseling and educating the patient/family/caregiver.
 - o Ordering medications, tests, or procedures.
 - Referring and communicating with other health care professionals (when not separately reported).
 - o Documenting clinical information in the electronic or other health record.
 - o Independently interpreting results (not separately reported) and communicating results to the patient/ family/caregiver.
 - o Care coordination (not separately reported).
- CMS is proposing to revise its policy to allow a practitioner to for a prolonged E/M as a split (or shared) visit.
- The agency proposes the two individual practitioners who performed the visit must be documented in the medical record and the individual who performed the substantive portion would be required to sign and date the medical record.
- The agency is proposing to create a modifier to be billed with these visits to identify the visits as split (or shared) visits.

Critical Care Services (CPT codes 99291-99292) (p. 254)

CMS includes proposals regarding critical care services and proposes to adopt the CPT prefatory language as the definition of critical care services: critical care is the direct delivery by a physician(s) or other qualified health professional of medical care for a critically ill/injured patient in which there is acute impairment of one or more vital organ systems, such that there is a probability of imminent or life-threatening deterioration of the patient's condition. The visit involves high complexity decision-making to treat single or multiple vital organ system failure and/or to prevent life-threatening deterioration of the patient's condition.

The agency also proposes to adopt CPT's listing of bundled services that are part of critical care visits to improve transparency and clarity of our policy for this service: 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. Any of the bundled services will not be separately billable when the practitioner is delivering a critical case service to a patient.

- Critical Care by a Single Physician or NPP: CMS proposes to adopt the CPT convention for critical
 care services furnished by a single physician or NPP: CPT code 99291 is used to report the first
 30-74 minutes of critical care on a given date, and that the code should be used only once per
 date even if the time spent by the practitioner is not continuous on that date.
- Critical Care Services Furnished Concurrently by Different Specialties: CMS is proposing that
 concurrent care occurs where more than physician or qualified NPP furnishes services to the
 same patient on the same day and can be covered when the services of each practitioner are
 medically necessary, and not duplicative.
- Critical Care Furnished Concurrently by Practitioners in the Same Specialty and Same Group
 (Follow-Up Care): CMS is proposing that the provider delivering the follow-up or subsequent
 care would report their time using CPT code 99292 for subsequent time intervals rather than
 CPT code 99291 the primary service code. However, should the initial practitioner not meet the
 time requirement to bill CPT code 99291 for initial care and another the practitioner in the same
 group and specialty who delivers critical care to the same patient on the same day, CMS
 proposes the time could be aggregated to meet the time requirement to bill for CPT code
 99291.
- Split (or Shared) Critical Care Services: Currently, critical care services cannot be billed as split
 (or shared) services, but CMS is proposing to reverse this policy in recognition of the growth of
 team-based care. Therefore, the agency is proposing the practitioner who furnishes the
 substantive portion of the cumulative critical care time would report the service for the care
 delivered to a patient by a physician and NPP on a given calendar date.
- Critical Care Visits and Same-Day Emergency Department, Inpatient, or Office/Outpatient Visits: CMS is proposing no other E/M visits can be billed for the same patient on the same day as the critical care services when the services are furnished by the same practitioner, or by practitioners in the same specialty in the same group. Thus, CMS is seeking comment on this proposal to better understand clinical practice for critical care, whether and how CMS could pay for E/M services furnished on the same date as critical care services when provided by the same practitioner, or practitioners in the same specialty within a group, while also reducing the potential for duplicative payment.
- Critical Care Visits and Global Surgery: The agency is proposing to bundle critical care visits with global surgical services.
- Documentation Requirements: CMS is proposing to require practitioners to document the total time that critical care services were provided by each reporting practitioner in the medical record as well as the services were medically reasonable and necessary.

Payment for the Services of Teaching Physicians (p. 268)

CMS policy states teaching physicians can bill for services only if they are present for the key or critical portion of the service if a resident participates in a teaching setting. Payment can also be provided if a teaching physician has a "virtual presence" for services delivered in training sites outside of metropolitan statistical areas. In this rule, CMS is proposing only the time a teaching physician was present can be included when total time is used to determine the outpatient E/M visit level.



Under the primary care exception, the agency is proposing only medical decision-making (MDM) can be used to select outpatient E/M visit level. Thus, CMS is seeking comment on this proposal, including on the assumption that MDM is a more accurate indicator of the appropriate level of the visit relative to time in the context of the primary care exception for services furnished by residents and billed by teaching physicians in primary care centers. CMS is also seeking comment on whether time is an accurate indicator of the complexity of the visit and how teaching physicians might select office/outpatient E/M visit level using time when directing the care of a patient that is being furnished by a resident in the context of the primary care exception.

Vaccine Administration Services: Comment Solicitation: Medicare Payments for Administering Preventive Vaccines (p. 297)

Medicare Part B Payment for Vaccines

In recent years, stakeholders have expressed concerns about the reduction (approximately 30 percent) in Medicare payment rates for the service to administer preventive vaccines covered by Medicare Part B under section 1861(s)(10) of the Social Security Act, including the influenza, pneumococcal, and hepatitis B virus (HBV) vaccines. The CARES Act included a provision regarding the COVID-19 vaccine and its administration. On March 15, 2021, CMS announced an increase in the payment rate for administering a COVID-19 vaccine to \$40 per dose, effective for doses administered on or after March 15, 2021.

CPT Code	Procedure Name	National Payment Amount For Physicians on or After March 15, 2021	National Payment Amount for Physicians Before March 15, 2021
0001A	Pfizer-Biontech Covid-19 Vaccine Administration – First Dose	\$40.00	\$16.94
0002A	Pfizer-Biontech Covid-19 Vaccine Administration – Second Dose	\$40.00	\$28.39
0011A	Moderna Covid-19 Vaccine Administration – First Dose	\$40.00	\$16.94
0012A	Moderna Covid-19 Vaccine Administration – Second Dose	\$40.00	\$28.39
0031A	Janssen/I&I Covid-19 Vaccine Administration	\$40.00	\$28.39

TABLE 22: Established Payment Rates for COVID-19 Vaccine Administration Services

In this proposed rule, CMS is requesting feedback from stakeholders that would support 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. CMS believes answers to the following questions would assist them in establishing payment rates for these services that could be appropriate for use on a long-term basis.

• What are the different types of providers and suppliers that furnish preventive vaccines, and have these types of providers/suppliers changed as a result of the PHE for COVID19? (CMS notes that their claims data reflect the type of Medicare enrollment for those billing for the vaccine administration, but are particularly interested in understanding additional, specific characteristics of the providers and suppliers that may not be distinguishable under the more general Medicare enrollment data.) CMS is also interested in whether different providers and suppliers furnish different aspects of the vaccine administration for the same beneficiary.

 $^{^1\,}https://www.cms.gov/newsroom/press-releases/biden-harris-administration-increases-medicare-payment-life-saving-covid-19-vaccine$



- What are the differences in incurred costs of furnishing flu, pneumonia and HBV vaccines compared to furnishing COVID-19 vaccines? Are there differences in the costs (per dose or otherwise) of furnishing a one-dose vaccine product vs. a two-dose vaccine product? Also, are there differences in cost of administering preventive vaccines furnished under the Part D benefit, such as the shingles vaccines, compared to those furnished under Part B?
- What are the resource costs that physicians, NPPs, mass immunizers and certain other suppliers incur when furnishing vaccines safely and effectively? CMS is interested in specific information on costs related to staffing/labor, infrastructure, patient onboarding/enrollment, vaccine storage and handling, vaccine procurement and coordination, supplies, CDC and state reporting requirements, patient counseling about safety and efficacy, and other costs CMS may not have considered. CMS is also interested in specific resource costs per vaccine dose within each cost category, if that is available.
- What are the impacts of the PHE for COVID-19 on resource costs incurred by vaccination providers, and do stakeholders envision that these impacts will continue after the PHE has ended? Following the end of the PHE, do you expect that the same types of vaccination providers and suppliers will continue to administer vaccines, or do you envision that this will change (if so, how, and what would be the primary factors driving the change)?
- As described previously, Medicare has generally relied on the PFS methodology for setting
 payment rates for HCPCS codes G0008, G0009 and G0010. How should Medicare assess costs
 associated with furnishing these preventive vaccines outside of the physician office setting, such
 as in pharmacies, mass immunization sites, mobile vaccine clinics or other locations? In addition,
 CMS understands that there could be administrative burden associated with the routine
 collection of cost data to support more accurate rate-setting for suppliers that are vaccinating
 patients. Are there other ways to update and validate costs for a broader range of entities using
 existing data?
- Payment rates for vaccine administration currently vary by setting. For HCPCS codes G0008, G0009 and G0010, the CY 2021 national average payment rate for physicians, practitioners and other suppliers is \$16.94, which is geographically adjusted, while for hospital outpatient departments it is \$40. However, for COVID-19 vaccine administration, Medicare now pays \$40 per administration in all settings, unless the vaccine in administered under certain circumstances in the beneficiary's home or residence (as discussed in more detail below). Should Medicare continue to pay differently for non-COVID-19 preventive vaccines furnished in certain settings or under certain conditions? If not, what factors contribute to higher costs for administration of non-COVID-19 vaccines that are not currently reflected in the Medicare payment rates?
- Should CMS use a different process to update the payment rates for administration of the preventive vaccines described in section 1861(s)(10) of the Act on an annual basis?
- In the last few years CMS has also crosswalked vaccine administration CPT codes 90460 (Administration of first vaccine or toxoid component through 18 years of age with counseling), 90461 (Administration of vaccine or toxoid component through 18 years of age with counseling), 90471 (Administration of 1 vaccine), 90472 (Administration of vaccine), 90473 (Administration of 1 nasal or oral vaccine), and 90474 (Administration of nasal or oral vaccine) to the same rate used by G0008, G0009 and G0010. How should Medicare address payment rates for these CPT codes under the PFS?
- Are there major differences between what Medicare pays physicians, NPPs and mass immunizers for non-COVID-19 preventive vaccine administration and what commercial insurers



pay? To the extent possible, CMS is also interested in feedback on specific rates used by other insurers.

Payment for COVID-19 Vaccine Administration in the Home

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. Under this new policy, providers and suppliers that administer a COVID-19 vaccine in a beneficiary's home under certain circumstances can bill Medicare for one of the existing COVID-19 vaccine administration CPT codes 0001A, 0002A, 0011A, 0012A, and 0031A, along with an add-on code, HCPCS code M0201 (COVID-19 vaccine administration inside a patient's home; reported only once per individual home per date of service when only COVID-19 vaccine administration is performed at the patient's home) under circumstances outlined in the proposal. Providers and suppliers administering a COVID-19 vaccine in the home can be paid a national average payment \$75.50 dollars per dose (\$40 for COVID-19 vaccine administration and \$35.50 for the additional payment for administration in the home).

In announcing the add-on payment for in-home COVID-19 vaccine administration, CMS noted these policies were established on a "preliminary basis to ensure access to COVID-19 vaccines during the public health emergency" and that they will continue to evaluate the needs of Medicare patients and these policies, and will address them in the future, as needed.

Monoclonal Antibodies Used to Treat COVID-19

During the COVID-19 pandemic, the Food and Drug Administration (FDA) authorized several monoclonal antibody products to treat COVID-19. CMS ultimately decided to cover and pay for these products under the COVID-19 vaccine benefit under section 1861(s)(10) of the Act – meaning that Medicare beneficiaries are not responsible for any cost sharing for the product or the service to administer it. In this proposed rule, CMS is seeking feedback on the following:

- The agency's approach to coverage and payment for COVID-19 monoclonal antibody products under the COVID-19 vaccine benefit;
- Whether the agency should treat monoclonal antibody products the same way they treat other physician-administered drugs and biologicals under Medicare Part B; and
- Information on the resource costs to administer COVID19 monoclonal antibody products, such as costs associated with infrastructure, clinical labor, and equipment, including personal protective equipment.

Payment for Medical Nutrition Therapy Services and Related Services (p. 316)

CMS is proposing to update the payment regulation for medical nutrition therapy (MNT). These updates are aimed at providing clarification that MNT services are, and have been, paid at 100 percent (instead of 80 percent) of 85 percent of the PFS amount, without cost sharing. The agency acknowledges that they neglected to update this regulation when the Affordable Care Act (ACA) excepted both coinsurance and deductible for preventive services that have a grade of A or B from the United States Preventive Services Task Force, and MNT services received a grade of B.

² https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment



Medical Nutrition Therapy (p. 422)

CMS is proposing to remove the requirement that MNT referral be made by what CMS calls the "treating physician." Current statute provides coverage of MNT services that may only be provided by a registered dietitians/nutrition professionals when referred by a physician. The agency also establishes the professional qualifications required of dietitians/ nutrition professional and proposes to establish regulations for registered dietitians/nutrition professionals, like established regulations for other NPPs.

Medicare Diabetes Prevention Program (MDPP) (p. 560)

CMS established the MDPP expanded model to prevent or delay onset of type 2 diabetes among eligible Medicare beneficiaries diagnosed with pre-diabetes. MDPP services are furnished in community and health care settings by organizations that enroll in Medicare as MDPP suppliers, a new supplier type, even if they have an existing Medicare enrollment as another supplier type. In this proposed rule, CMS is proposing to amend certain MDPP expanded model policies to enhance MDPP supplier enrollment, increase beneficiary access to MDPP services, and ultimately reduce the incidence of diabetes in eligible Medicare beneficiaries. Specifically, CMS is proposing to make the following changes:

- Waive the provider enrollment fee for all organizations that submit an application to enroll in Medicare as an MDPP supplier on or after January 1, 2022. CMS waived this fee during the COVID-19 PHE and found that there was a significant increase in provider enrollment and is now proposing to do so permanently.
- Under current regulations, MDPP suppliers are required to offer up to 2 years of MDPP services to eligible MDPP beneficiaries. This includes the Core sessions phase (Months 1-6), Core Maintenance sessions phase (Months 7-12), and the Ongoing Maintenance sessions phase (Months 13-24). CMS is proposing to shorten the current MDPP services period by one year by removing the Ongoing Maintenance phase. If this proposal is finalized, MDPP beneficiaries who were participating in the MDPP model on or before December 31, 2021, are still allowed to continue participating in the Ongoing Maintenance phase if they maintain 5 percent weight loss and meet the necessary attendance requirements.
- CMS is proposing to redistribute a portion of the Ongoing Maintenance sessions phase performance
 payments to certain Core and Core Maintenance session performance payments consistent with the
 removal of the Ongoing Maintenance phase. CMS will increase performance payments for MDPP
 beneficiary achievement of the 5 percent weight loss goal, and the continued attendance
 requirements during each core maintenance interval. The table below shows the current 2021
 performance payments and the proposed performance payments for MDPP beneficiaries who start
 their first core service on or after January 1, 2022.



Payment Description	Current	Proposed
Core Sessions (Months 1-6)		
Attend 1 Core Session or Bridge Payment		\$26
Attend 4 Core Sessions		\$78
Attend 9 Core Sessions		\$130
Core Maintenance (CM) Sessions (Months 7-12)		
Attend 2 Core Maintenance Sessions (No 5% WL) in CM Interval 1 (Months 7-9)	\$15	\$52
Attend 2 Core Maintenance Sessions (5% WL) in CM Interval 1 (Months 7-9)		\$106
Attend 2 Core Maintenance Sessions (No 5% WL) in CM Interval 2 (Months 10-12)		\$52
Attend 2 Core Maintenance Sessions (5% WL) in CM Interval 2 (Months 10-12)		\$106
5% WL Achieved from baseline weight		\$189
9% WL Achieved from baseline weight		\$26
Ongoing Maintenance Sessions (Months 13-24)		
Attend 2 Ongoing Maintenance (OM) Sessions in OM Interval 1 (Months 13-15)		
Attend 2 Ongoing Maintenance Sessions in OM Interval 2 (Months 16-18)		
Attend 2 Ongoing Maintenance Sessions in OM Interval 3 (Months 19-21)		
Attend 2 Ongoing Maintenance Sessions in OM Interval 4 (Months (22-24)		
Total Maximum Payment*	\$704	\$661

Physician Self-Referral Updates (p. 611)

In December 2020, CMS published the Modernizing and Clarifying the Physician Self-Referral Regulations final rule. This rule established and revised a number of exceptions to the physician self-referral law. This final rule also revised several definitions for fundamental terminology related to the law, including the definition of an "indirect compensation arrangement." To align with this final rule and concerns that have been expressed by stakeholders, CMS is proposing to revise the regulation that sets forth the conditions for "indirect compensation arrangements." Under this revision, an unbroken chain of financial relationships between a physician and an entity would be an indirect compensation arrangement for purposes of the physician self-referral law if the unit of compensation received by the physician (or immediate family member) is payment for anything other than services personally performed by the physician (or immediate family member). This would include an arrangement for the rental of office space or equipment.

Quality Payment Program Updates

MIPS Eligible Clinician (p. 710)

In response to stakeholder feedback, CMS proposes to revise the definition of a MIPS eligible clinician to include clinical social workers and certified nurse mid-wives. CMS also proposes to automatically reweight the promoting interoperability performance category to zero percent for clinical social workers.

MIPS Value Pathways (p. 716)

In CY 2020, CMS introduced the MIPS Value Pathway (MVP) framework, intended to replace the current MIPS. CMS continues to believe that transitioning to MVPs will improve value, reduce burden, inform patient choice in selecting clinicians, and reduce barriers to facilitate movement alternative payment models (APMs). CMS is focused on the following guiding principles to introduce and implement MVPs:

1. MVPs should consist of limited, connected complementary sets of measures and activities that are meaningful to clinicians. This will reduce clinician burden, align scoring, and lead to sufficient comparative data.



- MVPs should include measures and activities that result in providing comparative performance data, which is valuable to patients and caregivers in evaluating clinician performance and making choices about their care. MVPs will enhance this comparative performance data as they allow subgroup reporting that comprehensively reflects the services provided by multispecialty groups.
- MVPs should include measures selected using the Meaningful Measures approach and, wherever possible, the patient voice must be included, to encourage performance improvements in high priority areas.
- 4. MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.
- 5. MVPs should support the transition to digital quality measures

MVP Development Criteria (p. 763)

In last year's final rule, CMS established a specific set of criteria to be used in the development and selection of MVPs. In this proposed rule, CMS is proposing the following additions to the MVP development criteria beginning with the CY 2022 performance year:

- MVPs must include at least one outcome measure that is relevant to the MVP topic.
- Each MVP that is applicable to more than one clinician specialty should include at least one outcome measure that is relevant to each clinician specialty included.
- In instances when outcome measures are not available, each MVP must include at least one high priority measure that is relevant to the MVP topic.
- Allow the inclusion of outcomes-based administrative claims measures within the quality component of an MVP.
- Each MVP must include at least one high priority measure that is relevant to each clinician specialty included.
- To be included in an MVP, a qualified clinical data registry (QCDR) measure must be fully tested.

MVP Implementation Timeline (p. 729)

In the CY 2021 final rule, CMS delayed the implementation of the MVPs until the CY 2022 performance period, due to the COVID-19 pandemic. In this proposed rule, CMS is continuing to move forward with the development of MVPs and proposes to delay the transition to MVPs to the CY 2023 performance year. CMS is proposing the following MVP implementation timeline:

- CY 2023 performance period the initial set of MVPs will be available for reporting and that reporting is voluntary.
- CY 2024-2027 performance periods the MVP portfolio will be updated to include new MVPs that are available for reporting and MVP reporting is still voluntary.
- The end of the CY 2027 performance period CMS will sunset traditional MIPS.
- CY 2028 performance period and subsequent years CMS will require mandatory MVP reporting.

CMS seeks feedback on this proposed timeline. CMS also requests comments on the factors they should monitor and use to determine stakeholder readiness to sunset traditional MIPS and fully transition to MVPs.



Defining the Term "MVP Participant" (Page 727)

For the CY 2023 and CY 2024 performance periods, CMS is proposing to define the term "MVP Participant" to mean: an individual MIPS eligible clinician, multispecialty group, single specialty group, subgroup (which will be defined separately), or APM Entity. For the CY 2025 performance period and all future years, CMS proposes "MVP Participant" to mean: an individual MIPS eligible clinician, single specialty group, subgroup, or APM Entity. This change would account for CMS' proposal for multispecialty groups to be required to report as subgroups beginning with the CY 2025 performance period.

Subgroups (p. 744)

CMS is proposing to establish subgroup reporting. The agency proposes the following definition for subgroups: "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 (NPI)."

To participate as a subgroup, each subgroup would be required to:

- Identify the MVP the subgroup will report;
- Identify one population health measure included in the MVP, and if applicable, any outcomesbased administrative claims measure on which the subgroup intends to be scored, if available;
- Identify the clinicians in the subgroup by TIN and NPI; and
- Provide a plain language name for the subgroup for purposes of public reporting.

CMS seeks comment on how subgroups should be structured, assessed, and scored in the future as the implementation of MVPs continue.

MVP Participant Registration (p. 784)

CMS proposes that an MVP Participant would be required to register for the MVP between April 1 and November 30 of the current performance year. Therefore, to be eligible for the CY 2023 performance period, a participant must register by November 20, 2023. Further, at the time of registration, CMS proposes that the MVP participant must select (1) the MVP they intend to report, (2) one population health measure, and (3) any outcomes-based administrative claims measure on which the MVP Participant intends to be scored, if available within the MVP.

Proposed MVPs (p. 774)

CMS plans to gradually implement MVPs for specialties and subspecialties that participate in the MVP program. For the CY 2023 performance year, CMS is proposing to implement the following MVPs:

- 1. Rheumatology
- 2. Stroke Care and Prevention
- 3. Heart Disease
- 4. Chronic Disease Management
- 5. Emergency Medicine
- 6. Lower Extremity Joint Repair
- 7. Anesthesia

Each proposed MVP includes a specific set of measures and activities from the quality performance category, improvement activities performance category, and the cost performance category. CMS also includes a "foundational layer" of measures which includes population health measurers and promoting



interoperability performance category measures. Beginning on Page 1721 of the proposed rule, CMS defines the seven proposed MVPs in more detail.

Proposed MVP Reporting Requirements (p. 783)

CMS proposes the following MVP reporting requirements for all MVP participants for the four MIPS performance categories:

- Quality Performance Category An MVP Participant selects four quality measures, and one
 must be an outcome measure (or a high priority measure if an outcome is not available or
 applicable).
- Improvement Activities Performance Category The MVP Participant must select:
 - o 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.
- Cost Performance Category An MVP Participant is scored on the cost measures that are included in the MVP that they select and report.
- Foundational Layer
 - Population Health Measures An MVP Participant selects one population health measure, at the time of MVP registration, to be scored on.
 - o Promoting Interoperability (PI) Performance Category An MVP Participant is required to meet the Promoting Interoperability performance category requirements.

CMS is proposing to align the MVP scoring policies with those used in traditional MIPS. CMS also proposes to provide comparative performance feedback within the annual performance feedback to show the performance of similar clinicians who report on the same MVP.

Health Equity Measures in MVPs – Request for Information (p. 772)

CMS aims to close the health equity gap in the agency's clinician quality programs. CMS believes there is value in including quality measures that capture health equity in each MVP and they intend to prioritize the development of health equity measures through future cycles of measure development. As such, CMS requests feedback on the following:

- Should health equity measures be developed in a manner to be broadly applicable to the various specialties and subspecialties that participate in MIPS?
- Is there value in the development of more specialty specific health equity measures?
- Considering MIPS and MVPs includes several specialties and subspecialties, what factors should be considered when developing a health equity measure?
- Should CMS include a health equity measure in the foundational layer of all MVPs, as a required measure, in the future? If not, why not?

MIPS Cost Performance Category Updates (p. 841)

CMS proposes several updates to the cost performance category, including five new episode-based cost measures for melanoma resection, colon and rectal resection, sepsis, diabetes, and asthma/COPD. Each of these new episode-based measures will have a 20-case minimum, with the exception of melanoma resection, which has a 10-case minimum. CMS is also seeking comment on the process of cost measure development, including comment on measurement prioritization, priority areas for future episode-based measurement development, standards for measure construction and measure component, and



the challenges that stakeholders encounter in development of cost measures. Additionally, CMS proposes to assign a zero percent weight to the cost performance category for 2020 PY/CY2022 payment year due to the ongoing public health emergency. CMS is seeking comment on additional circumstances that would limit the ability to calculate cost measure scores to inform decision-making on cost re-weighting in the future.

MIPS Promoting Interoperability Performance Category (p. 887)

CMS proposes several revisions to reporting requirements, including revising requirements for the public health and clinical data exchange objective; add a requirement that patient have access to their health information indefinitely for encounters on or after January 1, 2016; require MIPS eligible clinicians to attest to conducting an annual assessment of SAFER Guides beginning in the CY 2022 performance period; and modifying the prevention of information blocking attestation statements to distinguish the attestation from separate requirements under the Office of the National Coordinator for Health Information Technology.

MIPS Quality Performance Category Updates (p. 943)

CMS proposes to remove end-to-end electronic reporting and the high-priority measure bonus points as well as the 3-point floor for scoring measures. CMS also proposes to use alternative period benchmarks, such as calendar year 2019 for scoring quality measures in the 2022 performance period, pending analysis of the 2020 performance period data. CMS also proposes to extend the CMS Web Interface as a quality reporting option for registered groups, virtual groups, or other APM entities for the 2022 performance period.

Performance Category Weights (p. 988)

The 2022 performance year/2024 payment year performance weights, specified in statute and codified in the 2022 PFS, are:

- 30% for the quality performance category;
- 30% for the cost performance category;
- 15% for the improvement activities performance category;
- 25% for the promoting interoperability category.

Request for Information: Utilization Data (p. 1049)

CMS is seeking information on how CMS could make Public Use File utilization data published in the Provider Data Catalog more useful or accessible to patients, to inform the ways in which utilization data may be useful to patients and caregivers for their healthcare decisions.

Advanced Alternative Payment Models for 2022 QP Performance Period (p. 1227)

CMS expects the following APMs to be Advanced APMs for the 2022 QP Performance Period:

- Bundled Payments for Care Improvement Advanced Model;
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track);
- Global and Professional Direct Contracting Model;
- Kidney Care Choices Model (Kidney Care First; Professional Option and Global Option);
- Maryland Total Cost of Care Model (Care Redesign Program; Maryland Primary Care Program);
- Medicare Shared Savings Program (Basic Track Level E, and the ENHANCED Track);
- Oncology Care Model (Two-Sided Risk Arrangements);



- Primary Care First (PCF) Model;
- Radiation Oncology model; and,
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).

MIPS Improvement Activities Performance Category (p. 1695)

CMS proposes to add 7 new improvement activities, modify 15 improvement activities, and remove 6 previously adopted improvement activities:

New	- Create and implement an anti-racism plan	
Activities	s - Implement food insecurity and nutrition risk identification and treatment protocols	
	- Implementation of a trauma-informed care approach to clinical practice	
	- Promoting clinician well-being	
	- Implementation of a personal protective equipment plan	
	- Implementation of a laboratory preparedness plan	
	- Application of CDC's training for healthcare providers on Lyme disease	
Revised	- Engagement of new Medicaid patients and follow-up	
Activities	- MIPS eligible clinician leadership in clinical trials or community-based participatory	
Activities	research	
	- Use of certified HER to capture patient reported outcomes	
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	- Collection of and follow- up on patient experience and satisfaction data on beneficiary	
	engagement	
	- Evidence-based techniques to promote self-management into usual care	
	- Drug cost transparency	
	- Practice improvements that engage community resources to support patient health	
	goals	
	- Perioperative surgical home care coordination	
	- Provide 24/7 access to MIPS eligible clinicians/groups who have real-time access to	
	patient's medical records	
	- Use of telehealth services that expand practice access	
	- Use of toolsets or other resources to close health care disparities across communities	
	- Regular review practices in place on targeted patient population needs	
	- Consultation of the prescription drug monitoring program	
	- Measurement and improvement at the practice and panel level	
	- COVID-19 clinical data reporting with or without clinical trial	
Removed	- Regularly assess the patient experience of care through surveys, advisory councils	
Activities	and/or other mechanisms	
	- Participation in CAHPS or other supplemental questionnaire	
	- Use of tools to assist patient self-management	
	- Provide peer-led support for self-management	
	- Implementation of condition-specific chronic disease self-management support	
	programs	
	- Improved practices that disseminate appropriate self-management materials	
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