

AAOS Summary: CY 2022 Medicare Physician Fee Schedule Proposed Rule

To reference page numbers and tables referred to in the summary, please [open the complete rule](#).

High Level Takeaways

Payment: Decrease to the conversion factor, new potentially misvalued spinal procedure codes, split (shared) evaluation and management visits between a physician and a non-physician provider, independent billing by physician assistants, and continued temporary coverage for telehealth.

Health Policy: Updates to the physician self-referral law regarding an unbroken chain of financial relationships, delayed implementation of the Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging until at least 2023, and revisions to the CMS Open Payments Program.

Quality Payment Program: Merit Based Incentive Payment (MIPS) Value Pathway Program (MVP) implementation delayed until 2023, the proposed introduction of a lower extremity joint repair MVP, and proposed updates to quality reporting by Qualified Clinical Data Registries (QCDRs).

● **CY 2022 PFS Conversion Factor**

2022 Medicare conversion factor would be reduced by approximately 3.75% from \$34.8931 to \$33.5848. This is largely a result of the expiration of a 3.75% increase to the conversion factor at the end of calendar year 2021, as averted for 2021 by the Consolidated Appropriations Act.

Table 123 (pg. 1180) shows the CY 2022 PFS Estimated Impact on Total Allowed Charges by Specialty. For orthopaedic surgery, CMS estimates the combined impact of work, PE, and MP RVU changes on allowed charges is 1%.

However, it is to be noted that this estimate does not include the impact of the expiration of the 3.75% payment that was included in the CY 2021 fee schedule as mandated by the Consolidated Appropriations Act. **Once this is accounted for, orthopaedic surgery could see up to a 2.7% decrease in total allowed charges for CY 2022.**

● **Potentially Misvalued Services Under the PFS (section II.C.)**

A stakeholder nominated CPT code 22551 (Fusion of spine bones with removal of disc at upper spinal column, anterior approach, complex) “and common related services” as potentially misvalued.

Citing the CY 2021 PFS final rule (84 FR 84501) where CMS agreed with the public nomination of CPT code 22867 (Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level) as potentially misvalued, and discussed the relationship between CPT code 22867

and CPT code 63047 (Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; lumbar), this stakeholder suggests that there are additional CPT code values related to spine procedures that are in need of contemporaneous review with CPT code 22867.

The stakeholder believes that CMS has an interest in reviewing associated anterior cervical discectomy and fusion (ACDF) procedures as well and suggests that CPT code 22551 “and common related services” can result in cumulative RVUs that do not sufficiently reflect physician work, time, or outcomes.

● **Telehealth and Other Services Involving Communications Technology (section II.D.)**

Proposed changes to the Medicare Telehealth Service List

CMS has an established regulatory process for adding services to or deleting services from the Medicare telehealth services list. CMS assigns requests to two categories. Category 1 is for services that are similar to professional consultations, office visits, and office psychiatry services currently on the Medicare telehealth services list and Category 2 is for services that are not similar to those on the current Medicare telehealth services list.

For CY2021, CMS created a third category of criteria for adding services to the Medicare telehealth services list on a temporary basis following the end of the PHE for the COVID-19 pandemic. This new category describes services that were added to the telehealth services list during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition under the Category 1 or Category 2 criteria.

CMS received several requests to permanently add various services to the Medicare telehealth services (eg, physical therapy evaluation evaluations) list effective for CY 2022 but found that none of the requests met their Category 1 or Category 2 criteria for permanent addition to the Medicare telehealth services list.

“We propose to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023. This will allow us time to collect more information regarding utilization of these services during the pandemic, and provide stakeholders the opportunity to continue to develop support for the permanent addition of appropriate services to the telehealth list through our regular consideration process, which includes notice-and-comment rulemaking. By keeping these services on the Medicare telehealth services list through CY 2023, we will facilitate the submission of requests to add services permanently to the Medicare telehealth services list for consideration in the CY 2023 PFS rulemaking process and for consideration in the CY 2024 PFS rule.” (pg. 92)

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

CMS is seeking comment on the extent 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 physicians and practitioners anticipate relying on this flexibility after the end of the PHE.

CMS is also seeking comment on whether this flexibility should potentially be made permanent, resulting in the revision of 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 after the PHE for COVID-19, or if they should continue the policy in place for a short additional time to facilitate a gradual sunset of the policy.

CMS is soliciting comment on whether the current timeframe for continuing this flexibility, which is currently the later of the end of the year in which the PHE for COVID-19 ends or December 31, 2021, remains appropriate, or if this timeframe should be extended through some later date to facilitate the gathering of additional information in recognition that, due to the ongoing nature of the PHE for COVID-19, practitioners may not yet have had time to assess the implications of a permanent change in this policy.

Lastly, CMS seeks comment regarding 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. CMS recognizes that it may be inappropriate to allow direct supervision without physical presence for some services, due to potential concerns over patient safety if the practitioner is not immediately available in-person. If this policy is to be made permanent, CMS seeks comment on whether a service level modifier should be required to identify when the requirements for direct supervision were met using two-way, audio/video communications technology.

Interim Final Provisions in the CY 2021 PFS Final Rule

Based on support from commenters, CMS is proposing to permanently adopt coding and payment for CY 2022, 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*) as described in the CY 2021 PFS final rule.

● Valuation of Specific Codes (section II.E.)

Insertion of Interlaminar/Interspinous Device (CPT code 22867)

CMS is proposing the RUC-recommended work RVU of 15.00 for CPT code 22867 (Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level). The RUC is

not recommending changes to the current PE inputs, and CMS is not proposing any changes to the current PE inputs.

Treatment of Foot Infection (CPT codes 28001, 28002, and 28003)

CMS is proposing the RUC-recommended work RVU of 2.00 for code 28001 (Incision and drainage, bursa, foot) as well as the surveyed physician times for this 000-day global code.

CMS is *not* accepting the RUC recommended a work RVU of 3.50 for code CPT code 28002 (Incision and drainage below fascia, with or without tendon sheath involvement, foot; single bursal space). CMS is proposing a work RVU of 2.79 and the RUC surveyed physician times for this 000-day global code.

CMS is proposing the RUC-recommended work RVU of 5.28 and surveyed physician times for 000-day global code 28003 (Incision and drainage below fascia, with or without tendon sheath involvement, foot; multiple areas).

Arthrodesis Decompression (CPT codes 630XX and 630X1)

For CPT codes 630XX (Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)) and 630X1 (Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional segment (List separately in addition to code for primary procedure)), CMS disagrees with the RUC-recommended work RVUs of 5.55 and 4.44, respectively, stating these values are anomalously high in comparison to other similar add-on codes that have longer intraservice times.

They are proposing a work RVU of 3.08 for CPT code 630XX and a work RVU of 2.31 for CPT code 630X1. Additionally, the RUC did not recommend any direct PE inputs for these codes and we are not proposing any direct PE inputs.

Destruction of Intraosseous Basivertebral Nerve (CPT codes 646X0 and 646X1)

CMS is not proposing the RUC-recommended work value of 8.25 for CPT code 646X0 (Thermal destruction of intraosseous basivertebral nerve, inclusive of all imaging guidance; first two vertebral bodies, lumbar or sacral). CMS is proposing a work RVU of 7.15 based on a crosswalk to CPT code 63650 (Percutaneous implantation of neurostimulator electrode array, epidural) as they believe this crosswalk is a more accurate valuation for CPT code 646X0.

CMS is also *not* proposing the RUC-recommended work value of 4.87 for CPT code 646X1 (Thermal destruction of intraosseous basivertebral nerve, inclusive of all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure)). They are proposing a work RVU of 3.77 for CPT code 646X1 based on the

recommended increment of 3.38 RVUs below our proposed work RVU of 7.15 for CPT code 646X0.

CMS is proposing the RUC-recommended direct PE inputs without refinements for CPT code 646X0. CPT code 646X1 is an add-on code and does not have any direct PE inputs.

Trabecular Bone Score Codes (CPT Codes 77X01, 77X02, 77X03, and 77X04)

CMS is proposing the RUC-recommended work RVUs of 0.20 for CPT codes 77X01 (Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk) and 77X04 (Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk interpretation and report on fracture risk only, by other qualified health care professional).

CPT codes 77X02 (Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical preparation and transmission of data for analysis to be performed elsewhere) and 77X03 (Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical calculation only) are PE only codes; the RUC did not recommend and we are not proposing a work RVU for these codes.

Principal Care Management (PCM) and Chronic Care Management (CCM) Codes (CPT codes 99490, 99439, 99491, 99X21, 99487, 99489, 99X22, 99X23, 99X24, and 99X25)

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)).

CMS reviewed the RUC-recommended values for the 10 codes in the CCM family and are proposing to accept the recommended work values for the codes. CMS is also proposing the RUC recommended direct PE inputs without refinements. CMS further states that proposing to accept these updated values is consistent with their goals of ensuring continued and consistent

access to these crucial care management services and acknowledges our longstanding concern about undervaluation of care management under the PFS.

TABLE 12: CY 2022 CCM/CCCM/PCM Proposed Values

CPT Code	Short Descriptor	Current Work RVU	RUC-recommended Work RVU	CMS Proposed Work RVU
99490	CCM clinical staff first 20 min	0.61	1.00	1.00

99439	CCM clinical staff each add 20 min	0.54	0.70	0.70
99491	CCM physician or NPP work first 30 min	1.45	1.50	1.50
99X21	CCM physician or NPP work each add 30 min	new	1.00	1.00
99487	CCCM clinical staff first 60 min	1.00	1.81	1.81
99489	CCCM clinical staff each add 30 min	0.50	1.00	1.00
99X22 (currently G2064)	PCM physician or NPP work first 30 min	new	1.45	1.45
99X23	PCM physician or NPP work each add 30 min	new	1.00	1.00
99X24 (currently G2065)	PCM clinical staff first 30 min	new	1.00	1.00
99X25	PCM clinical staff each additional 30 min	new	0.71	0.71

Additionally, CMS is seeking comment on whether keeping professional PCM and CCM at the same value creates an incentive to bill CCM instead of billing PCM when appropriate. CMS is also interested in understanding more about the standard practice used by practitioners to obtain beneficiary consent for these services.

CMS is also proposing to adopt CPT codes 99X22 (PCM First 30 minutes provided personally by a physician or other qualified health care professional, per calendar month) and 99X24 (PCM First 30 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month) to replace HCPCS codes G2064 and G2065 in the calculation of the rate for HCPCS code G0511 for General Care Management services billed by RHCs and FQHCs.

The payment rate for HCPCS code G0511 is calculated based on the average of the national non-facility PFS payment rate for care management and general behavioral health integration codes (CPT codes 99484, 99487, 99490, and 99491) as well as HCPCS codes G2064 and G2065 which describe PCM services billed under the PFS. The payment rate for HCPCS code G0511 is updated annually based on the PFS amounts for these codes.

● **Evaluation and Management Visits (section II.F.)**

Split (or Shared) Visits

CMS is proposing 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. Furthermore, CMS proposes to define split (or shared) visits as those that:

- Are furnished in a facility setting by a physician and an NPP in the same group, where the facility setting is defined as an institutional setting in which payment for services and supplies furnished incident to a physician or practitioner’s professional services is prohibited.
- Are furnished in accordance with applicable law and regulations, 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 (rather than as a split (or shared) visit).

CMS is also proposing to modify their policy 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. CMS proposes these modifications to the current policy and conditions of payment for split (or shared) visits to account for changes that have occurred in medical practice patterns, including the evolving role of NPPs as part of the medical team.

CMS proposes the definition of “substantive portion” as more than half of the total time spent by the physician and non-physician practitioner performing the visit. CMS states that they do not believe it would be appropriate to consider the performance of any portion of the visit - with or without direct patient contact - as a substantive portion. For instance, it would not be appropriate to consider a brief or minor interaction, with or without direct patient contact, such as where the physician merely “pokes their head” into the room, to be a substantive portion of the visit.

Therefore, “substantive portion” is defined as more than half of the total time spent by the physician and NPP performing the split (or shared) visit and CMS will revise their regulation to codify this definition. CMS recognizes that this policy would necessitate the practitioners’ tracking and documenting the time they spent for these visits but believe that practitioners are likely to increasingly time their visits for the purpose of visit level selection based on the changes to the CPT E/M Guidelines.

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). This would be consistent with the CPT E/M Guidelines stating that, for split (or shared) visits, when two or more individuals jointly meet with or discuss the patient, only the time of one individual should be counted).

Drawing on the CPT E/M Guidelines, CMS is proposing 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, they propose 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.

Critical Care Services

CMS is proposing to refine their policies regarding critical care services which will:

- To use American Medical Association (AMA) Current Procedural Terminology (CPT) prefatory language as the definition of critical care visits, including bundled services.
- To allow critical care services to be furnished concurrently to the same patient on the same day by more than one practitioner representing more than one specialty, and that critical care services can be furnished as split (or shared) visits.
- That no other E/M visit can be billed for the same patient on the same date as a critical care service when the services are furnished by the same practitioner, or by practitioners in the same specialty and same group to account for overlapping resource costs.
- That critical care visits cannot be reported during the same time period as a procedure with a global surgical period.

Teaching Physician Services

The AMA CPT office/outpatient E/M visit coding framework that CMS finalized for CY 2021, under which practitioners can select the office/outpatient E/M visit level to bill, was based either on use of the total time personally spent by the reporting practitioner or medical decision making (MDM). Under existing CMS regulations, if a resident participates in a service furnished in a teaching setting, a teaching physician can bill for the service only if they are present for the key or critical portion of the service. Under the so-called “primary care exception,” Medicare makes PFS payment in certain teaching hospital primary care centers for certain services furnished by a resident without the physical presence of a teaching physician.

CMS is proposing to clarify that the time when the teaching physician was present can be included when determining E/M visit level. Under the primary care exception specifically, only MDM would be used to select the visit level to guard against the possibility of inappropriate coding that reflects residents' inefficiencies rather than a measure of the time required to furnish the services.

- **Billing for Physician Assistant (PA) Services (section II.G.)**

CMS is proposing to implement section 403 of Division CC of the CAA that authorizes Medicare to make direct payment to PAs for professional services they furnish under Part B beginning January 1, 2022. Medicare currently can only make payment to the employer or independent contractor of a PA. Consequently, PAs could not bill and be paid by the Medicare program directly for their professional services; they also did not have the option to reassign payment for their services or to incorporate with other PAs to bill the program for PA services. Beginning January 1, 2022, PAs would be able to bill Medicare directly for their services and reassign payment for their services.

- **Therapy Services (section II.H.)**

CMS is implementing the final part of section 53107 of the Bipartisan Budget Act of 2018, which requires CMS, through the use of new modifiers (CQ and CO), to identify and make payment at 85% of the otherwise applicable Part B payment amount for physical therapy and occupational therapy services furnished in whole or in part by physical therapist assistants (PTAs) and occupational therapy assistants (OTAs), for dates of service on and after January 1, 2022.

For CY 2022, in response to numerous stakeholder questions and to promote proper therapy care, CMS is proposing to revise the *de minimis* standard established to determine whether services are provided "in whole or in part" by PTAs or OTAs. Specifically, CMS is proposing to revise the *de minimis* policy to allow a timed service to be billed without the CQ/CO modifier in cases when a PTA/OTA participates in providing care to a patient with a physical therapist or occupational therapist (PT/OT), but the PT/OT meets the Medicare billing requirements for the timed service without the minutes furnished by the PTA/OTA by providing more than the 15-minute midpoint (also known as the 8-minute rule).

Under this proposal, any minutes that the PTA/OTA furnishes in the scenarios described above would not matter for purposes of billing Medicare. In addition to cases where one remaining unit of a multi-unit therapy service to be billed, this revision to the policy would apply in a limited number of cases where more than one unit of therapy, with a total time of 24-28 minutes is being furnished. For these limited cases, CMS is proposing to allow one 15-minute unit to be billed with the CQ/CO assistant modifier and one 15-minute unit to be billed without the CQ/CO modifier in billing scenarios where there are two 15-minute units left to bill when the PT/OT and the PTA/OTA each provide between 9 and 14 minutes of the same service.

Overall, the *de minimis* standard would continue to be applicable in the following scenarios:

- When the PTA/OTA independently furnishes a service, or a 15-minute unit of a service “in whole” without the PT/OT furnishing any part of the same service.
- In instances where the service is not defined in 15-minute increments including: supervised modalities, evaluations/reevaluations, and group therapy.
- When the PTA/OTA furnishes eight minutes or more of the final unit of a billing scenario in which the PT/OT furnishes less than eight minutes of the same service.
- When both the PTA/OTA and the PT/OT each furnish less than eight minutes for the final 15-minute unit of a billing scenario.

● **Vaccine Administration Services (section II.J.)**

CMS is seeking feedback from stakeholders that would support the development of an accurate and stable payment rate for administration of preventative vaccines under Medicare Part B.

They are interested in detailed feedback on the following questions, which they believe would assist in establishing payment rates for these services that could be appropriate for use on a long-term basis.

1. 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 is also interested in whether different providers and suppliers furnish different aspects of the vaccine administration for the same beneficiary.
2. 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?
3. 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)?
4. 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? Understanding 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?
5. 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
6. vaccine is 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?
 7. 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?
 8. CMS has also cross-walked 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?
 9. 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 we are also interested in feedback on specific rates used by other insurers.

Payment for COVID-19 Vaccine Administration in the Home

CMS announced a new add-on payment, effective June 8, 2011, 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, 0031A) along with 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).

● Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (sections III.A., III.B., and III.C.)

There are several provisions that CMS is proposing that are aimed at bolstering the abilities of RHCs and FQHCs to furnish care to underserved Medicare beneficiaries. The following provisions demonstrate CMS's commitment to addressing health equities in rural and vulnerable populations.

Mental Health Services furnished via Telecommunications Technologies for RHCs and FQHCs

CMS is proposing to revise the current regulatory language for RHC or FQHC mental health visits to include visits furnished using interactive, real-time telecommunications technology. RHCs and FQHCs are not authorized to serve as distant site practitioners for Medicare telehealth services after the end of the COVID-19 public health emergency. However, this proposed change would allow RHCs and FQHCs to report and receive payment for mental health visits

furnished via real-time telecommunication technology in the same way they currently do when visits take place in-person, including audio-only visits when the beneficiary is not capable of, or does not consent to, the use of video technology.

Rural Health Clinic (RHC) Payment Limit Per-Visit

Section 130 of the CAA as amended by section 2 of P.L. 117-7, requires that, beginning April 1, 2021, independent RHCs and provider-based RHCs in a hospital with 50 or more beds receive an increase in their payment limit per visit over an 8-year period, with a prescribed amount for each year from 2021 through 2028. Then, in subsequent years, the limit is updated by the percentage increase in Medicare Economic Index (MEI). Also beginning April 1, 2021, section 130 as amended requires that a payment limit per-visit be established for smaller provider-based RHCs enrolled before January 1, 2021. Lastly, section 130 of the CAA subjects all newly enrolled RHCs (as of January 1, 2021, and after), both independent and provider-based, to a national payment limit per-visit.

Payment for Attending Physician Services Furnished by RHCs or FQHCs to Hospice Patients

CMS is proposing to implement section 132 of the CAA, which makes FQHCs and RHCs eligible to receive payment for hospice attending physician services when provided by a FQHC/RHC physician, nurse practitioner, or physician assistant who is employed or working under contract for an FQHC or RHC, but is not employed by a hospice program, starting January 1, 2022.

Concurrent Billing for Chronic Care Management Services (CCM) and Transitional Care Management (TCM) Services for RHCs and FQHCs

CMS is proposing to allow RHCs and FQHCs to bill for TCM and other care management services furnished for the same beneficiary during the same service period, provided all requirements for billing each code are met.

COVID-19 Vaccines Furnished in RHCs and FQHCs (Technical Updates)

Section 3713 of the CARES Act established Medicare Part B coverage and payment for a COVID-19 vaccine and its administration. CMS is proposing to make conforming technical changes to the regulatory text related to COVID-19 vaccines for RHCs and FQHCs.

Tribal FQHC Payments – Comment Solicitation

Outpatient clinics operated by a tribal organization under the Indian Self-Determination Education and Assistance Act or by an Urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act are eligible to become FQHCs. FQHCs are paid under the FQHC Prospective Payment System (PPS) under Medicare Part B based on the lesser of the FQHC PPS rate or their actual charges. There is an exception for payment under the FQHC PPS for certain tribal FQHCs in operation on or before April 7, 2000. Under the exception, grandfathered tribal FQHCs bill as if it were provider-based to an Indian Health Service (IHS) hospital and are paid the Medicare outpatient per visit rate, also referred to as the IHS all-inclusive rate (AIR).

CMS has received a request from the American Indian and Alaska Native community to amend its Medicare regulations to make all IHS- and tribally-operated outpatient facilities/clinics eligible for payment at the Medicare outpatient per visit/AIR, regardless of whether they were owned, operated, or leased by IHS. In addition, we have been asked to consider certain flexibilities regarding the cost reporting requirement for these types of facilities. Therefore, we are soliciting comment on these topics that could be used to inform future payment policy decisions.

● **Requiring Certain Manufacturers to Report Drug Pricing Information for Part B and Determination of ASP for Certain Self-administered Drug Products (sections III.D.1. and 2.)**

Per the Consolidated Appropriations Act passed at the end of 2020, the proposed rule “requires manufacturers without a Medicaid drug rebate agreement to report ASP information to CMS for calendar quarters beginning on January 1, 2022, for drugs or biologicals payable under Medicare Part B and described in sections 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act, including items, services, supplies, and products that are payable under Part B as a drug or biological” (pg. 361)

Additionally, “Starting with calendar quarters beginning on January 1, 2022, manufacturers will be required to report ASP for drugs and biologicals payable under Medicare Part B consistent with the statutory requirements of section 1847A(f) of the Act, regardless of whether they have Medicaid drug rebate agreements.” (pg. 362)

CMS proposes that “if the OIG study becomes available to the public in the first quarter of the calendar year, the lesser-of methodology would be applied to the payment limit calculation of the applicable billing and payment code in the third quarter ASP pricing file (in other words, the July ASP pricing file) and each quarter thereafter.” (pg. 373)

CMS also notes that “we will not apply the lesser-of methodology (that is, we will determine the payment allowance including all NDCs of the drug or biological product) if the drug and dosage form(s) represented by the billing and payment code are reported by the Drug Shortage list established under section 506E of the Federal Food, Drug, and Cosmetic Act (FFDCA) at the time that ASP payment limits are being finalized for the next quarter.” (pg. 375)

● **Medicare Part B Drug Payment for Drugs Approved under Section 505(b)(2) of the Federal Food, Drug, & Cosmetic Act (section III.E.) (pg. 377)**

Payment for multiple source drug codes—framework being shared for consideration in future policy making

“The first portion of the framework would compare certain qualities of the section 505(b)(2) drug product with drug products already assigned to an existing multiple source drug code.⁷⁸ This includes comparison of the: (1) active ingredient(s); (2) dosage form (if part of the drug product name); (3) salt form; and (4) other ingredients in the drug product formulation. The drug product assessment could result in a match or non-match designation.” (pg. 382)

● **Appropriate Use Criteria for Advanced Diagnostic Imaging (section III.F.) (pg. 391)**

“The fourth component of the Medicare AUC program is specified in section 1834(q)(5) of the Act, Identification of Outlier Ordering Professionals. The identification of outlier ordering professionals under this paragraph facilitates a prior authorization requirement that applies for outlier professionals beginning January 1, 2020, as specified under section 1834(q)(6) of the Act. Because we established a start date of January 1, 2020 for AUC consultation and reporting requirements, we did not identify any outlier ordering professionals by that date.

As such, implementation of the prior authorization component is delayed. However, we did finalize in the CY 2017 PFS final rule the first list of priority clinical areas to guide identification of outlier ordering professionals as follows:

- Coronary artery disease (suspected or diagnosed).
- Suspected pulmonary embolism.
- Headache (traumatic and non-traumatic).
- Hip pain.
- Low back pain.
- Shoulder pain (to include suspected rotator cuff injury).
- Cancer of the lung (primary or metastatic, suspected or diagnosed).
- Cervical or neck pain.

CMS 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.”

CMS is proposing that when the furnishing professional for advanced diagnostic imaging service performs at least one additional service under certain conditions, as listed in chapter 15, section 80.6.2-4 of the BPM, neither the ordering professional nor furnishing professional will be required to consult the AUC for those additional services. (pg. 392)

CMS is proposing to allow institutional claims with code 44 (inpatient admission changed to outpatient) to bypass the AUC claims processing edits (pg. 400)

“...claims that do not properly include AUC consultation information will not be paid once we fully implement the AUC claims processing edits. We are considering whether claims that do not pass the AUC claims processing edits, and therefore will not be paid, should be initially returned to the health care provider so they can be corrected and resubmitted, or should be denied so they can be appealed. On one hand, we expect there will be some errors in reporting AUC consultation information on claims, especially early on, and health care providers might find it helpful to have the opportunity to correct claims.

However, there may be situations in which the health care provider would prefer the claim be denied so they have an earlier opportunity to appeal. We are requesting comments to help us

better understand which path would be most appropriate once we fully implement the AUC program claims edits.

Additionally, we are requesting comments on whether the payment penalty phase should begin first with returning claims and then transition to denying claims after a period of time, which may be helpful to furnishing professionals and facilities as they become more proficient in submitting claims under the AUC program.” (pg. 401)

CMS will specify the start date for the AUC program claims processing edits to take effect. AUC program claims processing edits for the payment penalty phase will be applied to advanced imaging services which are furnished on or after the effective date of the claim edits. For those imaging services that are ordered prior to, but furnished on or after the effective date of the AUC program claims processing edits, the furnishing professional would apply the separate HCPCS modifier (pg. 402)

“For institutional claims, we propose to limit AUC program claims processing edits to apply only to type of bill 13x (hospital outpatient). This claim type code encompasses the hospital outpatient department and the emergency department which represent all applicable settings under the program that would bill Medicare using institutional claims.

For practitioner claims, we propose 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 as defined at § 414.94(b). Because these type of bill and place of service codes reflect the applicable settings within which advanced diagnostic imaging services must be furnished to be subject to the AUC program requirements, we believe setting these parameters will allow us to more accurately pay claims while avoiding the need for other types of professionals and facilities to append modifiers to their claims.” (pg. 405)

Request for Information

“We request feedback on whether additional scenarios require consideration and whether the proposed claims processing solutions will adequately address the issues raised. We also request feedback on areas that stakeholders believe need more education to inform our ongoing outreach and education efforts. While much of the discussion is about identifying claims that are not subject to the AUC program, we note that physicians and other practitioners, or providers submitting claims for advanced imaging services that are not subject to the AUC program can voluntarily report AUC consultation information. We intend to allow those claims to process through the system. We request commenters to provide additional information to assist us in developing edits that ensure only appropriate claims are subject to AUC claims processing edits.” (pg. 405)

The earliest date that the AUC program claims processing edits and payment penalty phase will begin is January 1, 2023, or if this is later than that, the January 1 that follows the declared end of the Public Health Emergency for COVID-19 (pg. 406)

● **Removal of Select National Coverage Determinations (section III.G.)**

“Eliminating an NCD that provides national coverage for items and services means that the item or service will no longer be automatically covered by Medicare (42 CFR 405.1060). Instead, the initial coverage determinations for those items and services will be made by local Medicare Administrative Contractors (MACs). On the other hand, removing an NCD that bars coverage for an item or service under title XVIII (that is, national noncoverage NCD), allows MACs to cover the item or service if the MAC determines that such action is appropriate under the statute.

Removing a national non-coverage NCD may permit more immediate access to technologies that may now be beneficial for some uses.” (pg. 408)

CMS will consider proposing the removal of an NCD if the following factors are considered:

- “We believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.
- The technology is generally acknowledged to be obsolete and is no longer marketed.
- In the case of a noncoverage NCD based on the experimental status of an item or service, the item or service in the NCD is no longer considered experimental.
- The NCD has been superseded by subsequent Medicare policy.
- The national policy does not meet the definition of an “NCD” as defined in sections 1862(l) or 1869(f) of the Act.
- The benefit category determination is no longer consistent with a category in the statute.”

CMS will also consider stakeholder feedback, claims data, and outdated documentation requirements.

Two NCDs are proposed for removal, one of which is relevant to orthopedics: NCD 220.6 Positron Emission Tomography (PET Scans)

CMS believes that local contractors should have the discretion to make the coverage decision to better serve the needs of the Medicare program, specifically for the current non-coverage of PET scans for non-oncologic indications (pg. 411)

● **Medicare Shared Savings Program (section III.J.) (pg. 434)**

“As explained in the CY 2021 PFS final rule, under the APP we are replacing the CAHPS for ACOs that was previously used in the Shared Savings Program with the CAHPS for MIPS.” (pg. 439)

“An ACO that does not meet the minimum sampling threshold to administer the survey will not receive a score for the CAHPS for MIPS survey under the APP. When an ACO fails to meet the sampling threshold and is unable to administer the survey, the ACO’s measure set will be scored accordingly, and the number of measures included in the calculation of the ACO’s quality performance score will be reduced from 10 to 9 measures or from 6 to 5 measures in the APP for PY 2021. This means that the denominator used to calculate the quality score will be lower, such that an ACO that falls below the minimum threshold will not be penalized for its inability to administer a CAHPS for MIPS survey.” (pg. 441)

The CMS Web Interface will be available as a collection type for the 2022 performance year for MIPS Groups, Virtual groups, and Shared Savings Program ACOs reporting under the APP. For Performance Year 2023, CMS is proposing that the CMS Web Interface would be a collection type under the APP only for Shared Savings Program ACOs.

To address stakeholder concerns about ACOs being ready to transition to eCQM/MIPS CQM quality measures, CMS proposes the following:

- “For performance year 2022, ACOs would either report the 10 CMS Web Interface measures or the 3 eCQMs/MIPS CQMs. Under the APP, all ACOs would administer the CAHPS for MIPS Survey and be scored on 2 administrative claims-based measures (calculated by CMS).
- For performance year 2023, ACOs would either report the 10 CMS Web Interface measures and at least one eCQM/MIPS CQM or the 3 eCQMs/MIPS CQMs. Under the APP, all ACOs would continue to administer the CAHPS for MIPS Survey and be scored on 2 administrative claims-based measures (calculated by CMS).”

CMS is proposing to freeze the quality performance standard at the 30th percentile MIPS quality performance category score for PY 2023.

For performance year 2024, the threshold for the quality performance standard CMS proposes an increase to the 40th percentile MIPS Quality performance category score.

The Agency has heard from stakeholders that the APP core quality measure set is not applicable to specialists, thus they are soliciting comments on reporting options for specialist providers within an ACO. (pg. 455)

- Specifically, they are “seeking comment on allowing ACO participant TINs to report either the eCQM/MIPS CQM measures in the APP measure set at the TIN level or the applicable MIPS Value Pathways, including how APP and MIPS Value Pathway data reported at the ACO participant TIN level could be aggregated in order to assess ACO quality performance” and seeking “input on the role specialists play in ACOs and what specialty measures in the current eCQM or MIPS CQM measure set should be considered for inclusion in the Shared Savings Program quality measure set in future performance years.”

- AAOs is one of the stakeholders that highlighted this issue in our CY 2021 MPFS Proposed Rule comment letter and plans to submit further feedback in response to CMS’s solicitation.

TABLE 24: Comparison of APP Reporting Requirements for Performance Year 2021 through 2024

	PY 2021	PY2022	PY2023	PY2024
Shared Savings Program ACO Quality Reporting requirements	ACOs are required to report the 10 measures under the CMS Web Interface or the 3 eCQM/MIPS CQM measures and administer the CAHPS for MIPS survey. CMS will calculate the HWR and MCC measures using administrative claims data. Based on the ACO’s chosen reporting option, either 6 or 10 measures will be included in calculating the ACO’s quality performance score.	Same as PY 2021	ACOs will be required to report either the 10 measures under the CMS Web Interface or the 3 eCQM/MIPS CQM measures. ACOs reporting the 10 CMS Web Interface measures must also report at least one of the 3 eCQM/MIPS CQM measures under the APP. ACOs will be required to field the CAHPS for MIPS survey. CMS will calculate the HWR and MCC measures using administrative claims data.	ACOs will be required to report on the 3 eCQM/MIPS CQM measures and field the CAHPS for MIPS survey. CMS will calculate the HWR and MCC measures using administrative claims data. All 6 measures will be included in calculating the ACO’s quality performance score.
Shared Savings Program ACO Quality Performance Standard	A quality performance score that is equivalent to or higher than the 30 th percentile across all MIPS Quality performance category scores. <u>Quality performance standard met:</u> ACOs are eligible to share in savings at the maximum sharing rate; ACOs in two-sided models share in losses based on their quality score or at a fixed percentage based on Track. <u>Quality performance standard not met:</u> ACOs are ineligible to share savings and owe the maximum amount of shared losses, if applicable.	Same as PY 2021. However, in order to encourage all payer measure reporting if the ACO reports all 3 eCQM/MIPS CQM measures under the APP, the ACO will satisfy the quality performance standard if it achieves a performance score that is equivalent to or higher than the 30 th percentile on at least one measure in the APP measure set.	Same as PY 2022. However, if an ACO does not report at least one eCQM/MIPS CQM measure, the ACO will not meet the quality performance standard.	A quality performance score that is equivalent to or higher than the 40 th percentile across all MIPS Quality performance category scores

● **Medicare Provider and Supplier Enrollment Changes (section III.N.1.)**

CMS is proposing to update the authority to deny or revoke Medicare enrollment based on the Office of Inspector General (OIG) Exclusion: (pg. 584)

“First, we propose to expand the categories of parties within the purview of these denial and revocation provisions to include excluded administrative or management services personnel who furnish services payable by a federal health care program, such as a billing specialist, accountant, or human resources specialist. This change would align with existing OIG guidance stating that providers and suppliers may not employ excluded persons to provide management or administrative services that are payable by a federal health care program.”

“To conform to our change described in the previous paragraph, we propose to replace this language with “other health care or administrative or management services personnel furnishing services payable by a federal health care program.”

“Third, § 424.535(e) states that if the revocation was due to adverse activity (sanction, exclusion, or felony) against an owner, managing employee, authorized or delegated official, medical director, supervising physician, or other personnel of the provider or supplier furnishing Medicare reimbursable services, the revocation may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that individual within 30 days of the revocation notification.”

“...we propose that if a provider or supplier receives written notice from CMS or its contractor that the provider’s or supplier’s billing privileges are to be or have been deactivated under § 424.540, the provider or supplier has 15 calendar days from the date of the written notice to submit a rebuttal to CMS. We believe that a 15-day period strikes an ideal balance between the need to expeditiously take measures to safeguard program integrity and the importance of ensuring that the provider or supplier has a reasonable time-period in which to submit a rebuttal.” (pg. 587)

“...we propose that CMS may, at its discretion, extend the 15-day time-period referenced in § 424.546(a)(1). This would permit CMS to account for special situations, such as the following: (1) a particularly and unusually complex deactivation case that perhaps warrants giving the provider or supplier more time to prepare its rebuttal; or (2) circumstances beyond the provider’s or supplier’s control prevents or would likely prevent the timely submission of its rebuttal.”(pg. 587)

“...we propose that any rebuttal must: (1) be in writing; (2) specify the facts or issues about which the provider or supplier disagrees with the deactivation’s imposition and/or effective date, as well as the reasons for disagreement; (3) submit all documentation the provider or supplier wants CMS to consider in its review of the deactivation; and (4) be submitted in the form of a letter that is signed and dated by the individual supplier (if the latter is enrolled as an individual physician or NPP), the authorized official or delegated official (as those terms are defined in § 424.502), or a legal representative (as defined in 42 CFR 498.10).” (pg. 587)

● **Provider/Supplier Medical Review Requirements: Addition of Provider/Supplier Requirements related to Prepayment and Post-payment Reviews (section III.N.2.)**

CMS is proposing key terms and definitions for prepayment and post-payment medical reviews, and also proposing language codifying the contractors’ authority to request additional documentation within established timeline and the provider’s responsibility to comply. (pg. 597)

- Post-payment review: “a review that occurs after payment is made on the selected claim to determine whether the initial determination for payment was appropriate”

- Pre-payment review: “a review that occurs before an initial determination for payment is made on the selected claim to determine whether payment should be made”

● **Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs) (section III.O.)**

“We are aware that the FDA recently announced the approval of a new, higher dose naloxone hydrochloride nasal spray product used to treat opioid overdose and that the newly approved product delivers 8mg of naloxone¹²¹. In the CY 2021 PFS final rule (85 FR 84683 through 84685), we finalized payment for HCPCS code G2215 (Take-home supply of nasal naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure). HCPCS code G2215 was priced based on an assumption of a typical case in which the beneficiary would be provided with a box of two 4mg nasal spray products.

At the time of drafting this proposed rule, we do not yet have any available pricing information for this newly approved product. However, in order to be able to make payment to OTPs under Medicare for this product, we are proposing to create a new G-code describing a take-home supply of this higher dose naloxone hydrochloride nasal spray product.” (pg. 606)

CMS is “proposing to allow OTPs to continue to furnish the therapy and counseling portions of the weekly bundles, as well as any additional counseling or therapy that is billed using the add-on code, using audio-only telephone calls rather than via two-way interactive audio/video communication technology following the end of the PHE for COVID-19 in cases where audio/video communication technology is not available to the beneficiary, provided all other applicable requirements are met.” (pg. 609)

CMS is also proposing “that after the conclusion of the PHE for COVID-19, when two-way interactive audio/video communication technology is used to furnish additional counseling and therapy services billed under the add-on code, OTPs would be required to append modifier 95 (Synchronous Telemedicine Service Rendered via Real-Time Interactive Audio and Video Telecommunications System) to the claim. We are not proposing to require the use of this modifier when counseling and therapy services included in the weekly bundle are furnished using two-way interactive audio/video communication technology. We recognize that it may be difficult to determine which modifier to use in cases where multiple services within the bundle are furnished using different modalities, therefore, we are limiting our proposal regarding the use of modifier 95 to claim lines for the counseling and therapy add-on code (HCPCS code G2080).” (pg. 610)

● **Updates to the Physician Self-Referral Regulations (section III.P.)**

“...we are proposing to revise the regulation to include as a potential indirect compensation arrangement any unbroken chain of financial relationships in which the compensation arrangement closest to the physician (or immediate family member of the physician) involves

compensation for anything other than services that he or she personally performs. This would include arrangements for the rental of office space or equipment that meet the other conditions of the regulation at § 411.354(c)(2), which would be subject to, among other requirements, the prohibition on percentage-based and unit-based (often referred to as “per click”) compensation formulas at § 411.357(p)(1)(ii) in the exception for indirect compensation arrangements (or the requirements of another applicable exception)” (pg. 614)

“To better align with our view regarding the reduced risk of program or patient abuse where compensation to a physician (or an immediate family member of a physician) is solely for services that he or she personally performs, the proposed revisions to § 411.354(c)(2)(ii) would require a two-step analysis of any unbroken chain of financial relationships in which the compensation paid under the arrangement closest to the physician (or immediate family member) is for anything other than services personally performed by the physician (or immediate family member), including, as noted above, arrangements for the rental of office space or equipment.

Specifically, we are proposing to revise the condition at § 411.354(c)(2)(ii)(A) to consider an unbroken chain of financial relationships between a physician and an entity that meets the other conditions of § 411.354(c)(2)(i) through (iii) to 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).” (pg. 623)

“As proposed, the condition at § 411.354(c)(ii)(A) would state that the referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the designated health services and the individual unit of compensation received by the physician (or immediate family member):

- (1) Is not fair market value for items or services actually provided;
- (2) Is calculated using a formula that includes the physician's referrals to the entity furnishing designated health services as a variable, resulting in an increase or decrease in the amount of compensation that positively correlates with the number or value of the physician's referrals to the entity;
- (3) Is calculated using a formula that includes other business generated by the physician for the entity furnishing designated health services as a variable, resulting in an increase or decrease in the amount of compensation per unit that positively correlates with the physician's generation of other business for the entity; or
- (4) Is payment for anything other than services personally performed by the physician (or immediate family member).” (pg. 623)

“With respect to compensation that is entirely paid per hour, per day, per month, per year, or per similar period of time, the individual unit of compensation is the smallest unit of time for which the compensation is paid.” (pg. 624)

“... compensation that has both a time-based unit component and a service based unit component—is appropriately analyzed by converting it to compensation for a unit of time for purposes of applying § 411.354(c)(2)(ii).” (pg. 626)

● **Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD Plan (section 2003 of the SUPPORT Act) (section III.Q.) (pg. 634)**

CMS proposes an additional one-year delay to EPCS compliance requirement. Due to the challenges of the COVID-19 pandemic faced by many prescribers, CMS proposes to change the compliance date to January 1, 2023. (pg. 642).

Though CMS will not take any enforcement action before January 1, 2023, they are putting forth a proposed compliance threshold in advance. Per the proposed rule, **“in order 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.”** (pg. 645)

During CY 2023, CMS proposes compliance actions consisting of notification letters sent to prescribers that CMS believes are violating the EPCS requirement. (pg. 657)

Proposed exceptions to the EPCS requirement are prescriptions issued when the prescriber and dispensing pharmacy are the same entity, cases where prescribers issue 100 or fewer Part D prescriptions, and cases of recognized emergencies and extraordinary circumstances.

● **Open Payments (section III.R.) (pg. 657)**

To clarify existing requirements as well as address stakeholder feedback, CMS proposes “the following revisions effective for data collection beginning in CY 2023 and reporting in CY 2024:

- (1) adding a mandatory payment context field for records to teaching hospitals;
- (2) adding the option to recertify annually even when no records are being reported;
- (3) disallowing record deletions without a substantiated reason;
- (4) updating the definition of ownership and investment interest;
- (5) **adding a definition for a physician-owned distributorship as a subset of applicable manufacturers and group purchasing organizations, for the purposes of Open Payments program reporting only, which definition would not apply for purposes of any other laws or regulations, including, but not limited to, section 1128B of the Act (the federal Anti-Kickback statute), the regulations at 42 CFR 1001.952, and materials interpreting the antikickback statute, such as Special Fraud Alerts; and section 1877 of the Act and the regulations at 42 CFR part 411, subpart J (collectively, the physician self-referral law);**
- (6) requiring reporting entities to disclose relationships they have with other companies for the purposes of transparent reporting;

- (7) disallowing publications delays for general payment records;
- (8) 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
- (9) removing the option to submit and attest to general payment records with an “Ownership” Nature of Payment category.” (pg. 660-661)

● **Updates to the Quality Payment Program (section IV.) (pg. 668)**

Merit-Based Incentive Payment System (MIPS)

Per statutory requirements, the cost and quality MIPS performance categories must be equally weighted beginning with the 2022 Performance Year. In this way, CMS is proposing the following performance category weights for Traditional MIPS participants reporting as individuals, groups, or virtual groups:

- Quality: 30% (decrease 10% from 2021)
- Cost 30% (increase 10% from 2021)
- Promoting Interoperability: 25% (no change from 2021)
- Improvement Activities: 15% (no change from 2021)
-

For those reporting Tradition MIPS as APM Entities and individuals, groups, and APM Entities reporting through the APM Performance Pathway (APP) there is no change to performance category weights. Cost continues to be weighted 0% for these reporting options.

CMS is proposing adding clinical social workers and certified nurse midwives as MIPS eligible clinician types for the 2022 Performance Year.

The concept of a subgroup reporting option, which would allow multispecialty groups to self-identify groups of clinicians within their organization that intend to report the same measures, is being introduced (pg. 744). Beginning with 2023 Performance Year, CMS proposes allowing voluntary subgroup reporting for the MVP and APP.

- CMS requests feedback on the future vision of subgroup reporting on pg. 762.

MIPS Quality Performance Category Updates

CMS proposes the following updates to the quality performance category:

Maintain the data completeness criteria threshold of at least 70 percent for 2021 and 2022 MIPS performance periods (2023 and 2024 MIPS payment years) and increase the data completeness criteria threshold to at least 80 percent for the 2023 MIPS performance period (2025 MIPS payment year).”

The addition of 5 new MIPS quality measures, the removal of 19 MIPS quality measures, and substantial changes to 84 MIPS quality measures. Details of quality measure updates are found in Appendix 1. (pg. 1380)

The following measures previously finalized in the Orthopaedic Surgery Specialty Measure Set are being considered for removal (pg. 1524):

- QID 021 - Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin

- QID 023 - Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients)
- QID 154 - Falls: Risk Assessment (topped out)
- QID 317 - Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

For new measures, CMS is proposing a 5-point payment floor for the first 2 MIPS performance years it is available.

For established measures (i.e. measures available for more than 2 performance years), CMS is proposing removal of the 3-point floor.

CMS is also proposing removing the 3-point floor for established measure without a benchmark and measures that do not meet the case minimum, except when reported by small practices.

The Agency plans to remove bonus points for end-to-end electronic reporting and reporting additional outcome/high priority beyond the 1 required.

MIPS Cost Performance Category Updates

CMS is proposing 5 new cost measures for the 2022 Performance Year – Asthma/COPD, Colon and Rectal Resection, Diabetes, Melanoma Resection, and Sepsis.

To increase the inventory of cost measures, CMS proposes a new process for cost measure development by stakeholders. (pg. 862) They seek stakeholder feedback on the proposed measure prioritization criteria as well as priority areas for future episode-based measure development. Cost measures submitted by stakeholders would still go through the Measures Under Consideration (MUC) process.

MIPS Improvement Activities Performance Category Updates

CMS is proposing 2 new criteria for new improvement activity nominations:

- Should not be duplicative to existing IA.
- Should drive improvements beyond the standard of care.

7 new IA measures are proposed, including 3 related to promoting health equity. There are 6 IA measures proposed for removal.

MIPS Promoting Interoperability Performance Category Updates

For the Public Health and Clinical Data Exchange Objective, CMS is proposing to require MIPS eligible clinicians to report the following two measures, unless an exclusion can be claimed:

- Immunization Registry Reporting
- Electronic Case Reporting

The three other optional measures – Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting – will be available for 5 bonus points.

For the Provide Patients Electronic Access to their Health Information measure, CMS is proposing a modification that would “require patient health information to remain available to the patient (or patient-authorized representative) to access indefinitely, starting with a date of service of January 1, 2016.” (pg. 894)

CMS is proposing a new PI measure, Safety Assurance Factors for EHR Resilience Guides (SAFER Guides), for which MIPS eligible clinicians must attest to conducting an annual assessment of the High Priority Guide of the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides).

CMS is proposing modifications to the Prevention of Information Blocking attestation to align with section 3022 of the PHS Act and the 21st Century Cures Act final rule. Similar modifications were proposed for the Medicare Promoting Interoperability Program in the FY 2022 IPPS/LTCH PPS proposed rule.

To better support small practices, CMS is proposing “to assign a weight of zero percent to the Promoting Interoperability performance category and redistribute its weight to another performance category or categories in the event no data is submitted.” (pg. 920) CMS states this flexibility is not intended to be permanent and will likely last “only a few years”.

Final MIPS Scoring Updates

Due to the ongoing effects of COVID-19, **CMS plans to continue doubling the complex patient bonus for the 2021 MIPS performance year/2023 MIPS payment year.** MIPS participants can earn up to 10 bonus point to their final score.

However, CMS is proposing changes to limit the bonus to clinicians who have a median or higher value for at least one of the two risk indicators (HCC and dual-eligible ratio) and they propose updating the formula to standardize the distribution of 2 two risk indicators so that the policy can target clinicians who have a higher share of socially and/or medically complex patients.

Beginning with the 2022 performance year, the performance threshold is statutorily required to be either the mean or median of the final scores for all MIPS eligible clinicians for a prior period.

In this way, CMS is proposing for the **2022 Performance Year that the performance threshold be set at 75 points.** This is the minimum final score required to avoid a negative payment adjustment on CY 2024 Medicare Part B claims.

The exceptional performers threshold is proposed for those scoring 89 points or more.

MIPS Value Pathways (MVPs)

Implementation of MIPS Value Pathways (MVPs) is being delayed again “to provide clinicians and third party intermediaries with sufficient time to prepare for a shift to this new

participation framework” (pg. 670). **CMS is now proposing MVP implementation beginning January 1, 2023.**

Within the proposed rule CMS lays out the timeline for MVP implementation (Table 31, pg. 731). **It is important to note, that CMS asserts their intent to eventually sunset the Traditional MIPS program and make MVP reporting mandatory.** They are considering mandatory MVP reporting beginning with the 2028 Performance Year.

The Agency has put forth an introductory set of 7 MVPs to be reportable starting with the 2023 Performance Year, **one of which is aimed at lower extremity joint repair.** See [Table F \(pg. 1740\)](#) for a complete list of proposed measures.

CMS is proposing to define an MVP participant as “an individual MIPS eligible clinician, multispecialty group, single specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories.” (pg. 728) By the 2025 Performance Year, they intend to require multispecialty groups to report as subgroups.

To incentivize MVP participation, CMS is encouraging “accrediting organizations such as specialty societies, to work with MVP submitters and consider whether CME credit or credit towards MOC could be offered for reporting MVPs.”

“To the extent feasible, MVPs should include a maximum of 10 quality measures and 10 improvement activities, to offer MVP Participants some choice without being overwhelming.” (pg. 765) However, this is not a strict requirement and CMS has indicated they intend to be flexible.

CMS is proposing that “MVPs must include at least one outcome measure that is relevant to the MVP topic, so MVP Participants are measured on outcomes that are meaningful to the care they provide.” (pg. 766) If a relevant outcome measure is not available, “each MVP must include at least one high priority measure that is relevant to the MVP topic, so MVP Participants are measured on high priority measures that are meaningful to the care they provide.” (pg. 767)

CMS proposes an annual process for maintenance of MVPs (pg. 773). As expected, updates will be made through the rulemaking process.

The following are proposed MVP reporting requirements for the quality, cost, and improvement activity performance categories:

- “Select and report, if applicable, 4 quality measures, including 1 outcome measure (or, if an outcome measure is not available, 1 high priority measure, included in the MVP, excluding the population health measure.” (pg. 775)
 - Under Traditional MIPS, participants are required to report 6 quality measures, thus reporting burden is reduced for MVP participants.

- CMS also believes “it would be appropriate to allow MVP Participants to select to be calculated on the outcomes-based administrative claims measure, at the time of MVP registration, and to allow that measure to meet the outcome measure requirement of MVP quality reporting.” (pg. 776)
 - It should be noted that if an MVP participant chooses to report an outcomes-based administrative claim measure to fulfill the outcome measure requirement, and the outcomes-based administrative claims measure does not meet the benchmark or case minimum, CMS is proposing that the MVP Participant would receive zero measure achievement points for that measure.
- If an MVP includes fewer than 4 quality measures with a Medicare Part B claims reporting option, small practices are allowed to report only those measures with a claims option without penalty.
- CMS proposes “that an MVP Participant is scored on the cost measures included in the MVP they select and report.” (pg. 776)
- From the set of Improvement Activities included in the MVP, CMS proposes that MVP participants “must report one of the following: two medium-weighted improvement activities; one high-weighted improvement activity; or participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice as described at (82 FR53652) and at § 414.1380(b)(3)(ii).” (pg. 777)
 - This proposal further alleviates reporting burden for MVP participants by reducing the IA reporting requirement of Traditional MIPS by half.
- CMS proposes “that MVP Participants must submit one population health measure of their choice from the list of finalized population health measures within the foundational layer of the MVPs”. (pg. 788)

Proposed MVP Reporting Requirements are summarized in Table 34. (pg. 783)

CMS is proposing a registration process through which MVP Participants would be required to notify the Agency of

- (1) MVP selection;
 - (2) population health measure selection;
 - (3) administrative claim-based quality measure selection, if applicable; and
 - (4) subgroup participation. (pg. 784)
- They are proposing a window for registration that begins on April 1 and ends of November 30 of the applicable performance year, unless otherwise specified by CMS. For example, if participating in an MVP in the 2023 performance year, an MVP participant would be required to register between April 1, 2023 – November 30, 2023.

CMS seeks to align MVP scoring with established Traditional MIPS scoring whenever possible, though there will be some differences in performance category denominators due to the reduced burden of MVP reporting (i.e. fewer required measures for quality and improvement activities). An example final score can be found in Table 38 (pg. 806).

CMS plans to provide comparative performance feedback, comparing the performance of like clinicians who report on the same MVP at the time of annual performance feedback for MVP participants. They request stakeholder input for future consideration on how actionable feedback may be provided.

APM Performance Pathway

In the APP measure set, CMS proposes replacing the Risk-standardized, All-cause Unplanned Admissions for Multiple Chronic Conditions for ACOs (MCC for ACOs) measure with the Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS (MCC for MIPS) measure beginning with the 2022 Performance Year.

As noted in the MSSP section above, the CMS Web Interface will be available as a collection type for the 2022 performance period for MIPS Groups, Virtual groups, and Shared Savings Program ACOs reporting under the APP. CMS had previously planned to sunset the CMS Web Interface option beginning in 2022.

Third Party Intermediaries (pg. 1016)

CMS is proposing a few changes to the third part intermediary general requirements:

- Must support MIPS reporting/submission for APM Entities. Third party intermediaries do not have to support submission of the Promoting Interoperability performance category for APM Entities.
- **“Beginning with the 2023 MIPS performance period/2025 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. QCDRs and qualified registries may also support the APP.” (pg. 1030)**
- CMS proposes that third party intermediaries must support subgroup reporting.

CMS is requesting general feedback on third party intermediaries that derive data from CEHRT (pg. 1032).

Updates Specific to QCDR & Qualified Registries

CMS is concerned about vendors self-nominating to achieve the QCDR title, but not actively participating in the MIPS program, thus they are proposing a two-tiered solution:

- 1) **“A new requirement to require QCDRs and qualified registries that have never submitted data since the inception of MIPS (2017 MIPS performance period/2019 MIPS payment year) through the 2020 MIPS performance period/2022 MIPS payment year, to submit a participation plan as part of their self-nomination for CY 2023. Exceptions to this requirement may occur if data is received for the 2021 MIPS performance period/2023 MIPS payment year.” (pg. 1034)**
- 2) **“A new requirement at paragraph (b)(3)(viii) to state, beginning with the 2024 MIPS performance period/2026 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan for CMS’s**

approval. For example, for the 2024 MIPS performance period/2026 MIPS payment year, vendors will be required to have submitted performance data for the 2021 and 2022 MIPS performance periods/2023 and 2024 MIPS payment years.” (pg. 1035)

Note: AAOS Registries have never submitted MIPS data directly to CMS. The above requirements could apply to AAOS if no participants submit MIPS data through our registries.

CMS is proposing to extend its current policy that permits collaboration among entities to create a QCDR to qualified registries.

To further clarify and align existing policy on data validation plans in the self-nomination process, CMS is proposing new requirement that “beginning with the CY 2023 MIPS performance period/2025 MIPS payment year, the QCDR or qualified registry must submit a data validation plan annually, at the time of self-nomination, for CMS’ approval, and may not change the plan once approved, without the prior approval of the agency.” (pg. 1037)

CMS proposes two new rejection criteria for QCDR measures:

- 1) The QCDR does not have permission to use a QCDR measure; and
- (2) The QCDR is not approved or not in good standing.

Related to QCDR measure inclusion in MVPs: “QCDRs must self-nominate as a QCDR and submit QCDR measures for CMS consideration within the 60-day self-nomination period that begins on July 1st of the calendar year prior to the applicable performance period and ending on September 1 of the same year. In order to determine whether a QCDR measure may be finalized within an MVP, we will need to receive QCDR measure testing data for review by the end of the self-nomination period, that is no later than September 1 of the year prior to the applicable performance period. We encourage, as feasible, that QCDRs share testing data for their fully tested QCDR measures at the time of MVP candidate submission which may be prior to the September 1st deadline. If a QCDR is unable to submit testing data to demonstrate that their QCDR measure is fully tested at the clinician level by end of the self-nomination period (September 1st) or does not otherwise meet our requirements, we will not finalize the inclusion of the QCDR measure within an MVP.” (pg. 769)

Requests for Information

Similar to the 2022 Inpatient Prospective Payment System Proposed Rule, CMS is issuing two Requests for Information (RFIs) within the scope of the Medicare Part B Quality Payment Program. CMS is issuing RFIs on Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs (pg. 676) and Closing the Health Equity Gap in CMS Clinician Quality Programs (pg. 698).

Public Reporting on the Compare Tools hosted by the U.S. Department of Health & Human Services (HHS)

CMS proposing the addition of facility affiliation, beyond hospital affiliation, to individual clinician pages on the HHS’s Compare Tools website. (pg. 1042)

They are also considering adding utilization data to help patients find providers who specialize (e.g. looking for an orthopaedic surgeon who specializes in knee arthroplasty). (pg. 1049)

Advanced Payment Models (APMs)

To account for changes in Qualifying Participant (QP) employment/affiliations, CMS proposes “to amend our APM Incentive Payment decision hierarchy to include an additional attempt to identify and pay, at each step, one or more solvent TINs associated with the QP during the payment year when no such TIN is identified for the QP in the base year.” (pg. 1057)

QP and Partial QP thresholds remain unchanged from 2021 performance year. In 2023 they will likely increase. See Table 63 (pg. 1061) for a detailed timeline of QP threshold updates.