Policy Update

CMS Releases CY 2022 Physician Fee Schedule Final Rule

On November 2, 2021, the Centers for Medicare & Medicaid Services (CMS) released the calendar *year (CY) 2022 Revisions to Payment Policies under the Physician Fee Schedule (PFS) and Other Changes to Part B Payment Policies [CMS-1751-F] Final Rule*, which includes policies related to Medicare physician payment and the Quality Payment Program (QPP). This year's final rule addresses telehealth and other COVID-19 flexibilities, updates to the underlying practice expense (PE) data that will impact payment rates, health equity, and enhancements and other changes to further develop physician quality initiatives.

These regulations reflect the goals and priorities of the Biden Administration. The final rule focuses on extending COVID-19 flexibilities and payment enhancements into 2022 and establishing policies that takes health equity into account. The PFS regulations are also a vehicle to implement several payment and related policies from recent legislation.

Key takeaways from the CY 2022 PFS Final Rule:

- The 2022 physician conversion factor (CF) is $33.5983. This represents a decrease of 3.71% from the 2021 CF of $34.8931. The 2022 anesthesia CF is $20.9343, in comparison to the 2021 CF of $21.5600, representing a decrease of 2.9%.
- Coverage for services temporarily added to the Medicare Telehealth Services List during the pandemic is extended from the end of the public health emergency (PHE) to the end of CY 2023.
- Clinical labor pricing data will be updated over a four-year period. This will help maintain stability by gradually phasing in the new data and will reduce the near-term impact on specialties experiencing negative effects due to the new data.
- Payment for services provided by physical therapy assistants and occupational therapy assistants (supervised by physical therapists or occupational therapist) is set at 85%, as required by statute.
- Enhanced payments for COVID-19 vaccine administration will continue through CY 2022.
- The Merit-based Incentive Payment System (MIPS) Value Pathways will launch in CY 2023.

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- The final regulations are available **here**.
- The press release is available **here**.
- The fact sheet is available **here**.
- The QPP factsheet is available **here**.

Read on for a topline summary of the major provisions in the final rule.

PFS Major Proposals

Conversion Factor

Medicare physician payment is based on the application of a dollar-based CF to work, PE and malpractice relative value units (RVUs), which are then geographically adjusted. Work RVUs capture the provider's time, intensity and risk. PE RVUs capture the cost of supplies, equipment and clinical personnel wages used to furnish a specific service. Malpractice RVUs capture the cost of malpractice insurance.

Key Takeaway: The CY 2022 CF represents a decrease of 3.71%. Congressional action required to avert the payment cut.

Medicare Physician CF (2017–2022)		
Year	**CF**	**Actual Update (%)**
Jan 1, 2017	35.8887	0.24
Jan 1, 2018	35.9996	0.31
Jan 1, 2019	36.0391	0.11
Jan 1, 2020	36.0896	0.14
Jan 1, 2021	34.8931	-3.32
Jan 1, 2022	**33.5983**	**-3.71**

The 2022 final physician CF is $33.5983. This represents a decrease of 3.71% from the 2021 CF of $34.8931. The final 2022 anesthesia CF is $20.9343, in comparison to the 2021 CF of $21.5600, representing a decrease of 2.9%.

The CF update is based on two factors: a 0% update is scheduled for the PFS in CY 2022[1], and a funding patch passed by Congress at the end of CY 2020 expires at the end of CY 2021. The Consolidated Appropriations Act (CAA) of 2021 funded a 3.75% positive payment adjustment, which helped mitigate some of the scheduled reductions to the CY 2021 CF. This update was only funded for CY 2021, and Congress will need to act in order to extend it through CY 2022 and beyond.

Unlike other Medicare payment systems that are tied to inflationary adjustments, the Medicare PFS is built on a budgetary rate-setting system that does not account for rising costs of care or changes in utilization. This has resulted in year-to-year instability in Medicare physician payment. One of the significant goals of the Medicare Access and CHIP Reauthorization Act (MACRA), which was signed into law in 2015 and implemented in 2017, was to provide stability to physician payment. Given that the physician CF has decreased by more than 6% since its implementation (from $35.8887 in 2017 to $33.5983 in 2022), MACRA is generally considered to have failed to accomplish that goal.

In addition to the reduction in the CF, physicians face other looming payment cuts that require congressional action in order to be averted. These payment reductions include expiration of the moratorium on Medicare sequestration at the end of CY 2021 (2%) and statutory sequestration cuts required by pay-as-you-go legislation (4%), which were triggered by the significant additional spending in the American Rescue Plan enacted in March 2021. If implemented, these cuts together with the CF update would result in an almost 10% percent across the board payment reduction to physician services.

[1] The Medicare Access and CHIP Reauthorization Act of 2015 established a 0% update for PFS services through 2025. Beginning in 2026, clinicians identified as qualified participants in an Advanced Alternative Payment Model will receive an annual 0.75% update, and all other clinicians will receive a 0.25% annual update.

These payment reductions come at a time when physician practices, hospitals that employ physicians and other healthcare stakeholders are facing uncertainty about the future of their pandemic recovery, including what flexibilities may continue beyond the PHE. These providers are also significantly challenged by other regulatory burdens (*e.g.*, prior authorization, interoperability requirements and participating in Medicare quality programs such as MIPS). In light of these burdens, the provider community continues to press Congress for relief from these payment cuts.

Congress has been engaged on this issue. Earlier this fall, 247 members of the US House of Representatives sent a letter to House leadership highlighting the increasing urgency around the aggregate payment cuts. Led by Reps. Ami Bera, MD (D-CA) and Larry Bucshon, MD (R-IN), the letter notes that despite the passage of MACRA and the attempted move away from fee-for-service, many specialties lack available alternative payment models or resources to implement true value-based care within their practices. The letter asked Congress to avert the forthcoming Medicare payment cuts by extending the 3.75% payment adjustment through 2022 to provide additional stability to the Medicare payment system until longer-term, systemic reforms can be made. There had been indications that Congress would not address the payment reductions until after the release of the final rule. Congress also has been focused on the passage of the infrastructure bill. With the release of the final rule, and as Congress nears resolution on the infrastructure bill, there likely will be more activity around addressing the looming physician payment cuts.

Specialty Impact

Key Takeaway: The final rule's impact ranges from -5% for Interventional Radiology and Vascular Surgery to +6% for Diagnostic Testing Facilities.

Actual payment rates are affected by a range of policy changes related to physician work, PE and malpractice RVUs. CMS summarized the aggregate impact of these changes in Table 136 in the final rule. While impact on individual practices will vary based on service mix, the table provides insight into the overall impact of the rule's policies for a specific specialty. Specialty impacts range from -5% for Interventional Radiology and Vascular Surgery to +6% for Diagnostic Testing Facilities.

Some of the differences in specialty impact are due to changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes and other changes to individual procedures. However, much of the aggregate impact for CY 2022 is driven by CMS's finalized proposal to update clinical labor pricing, which has led to decreases in payments for specialties with substantially lower average shares of direct costs attributable to clinical labor. These reductions impact PE RVUs (*e.g.* supplies, clinical labor and equipment) and therefore largely affect office-based specialties. The agency's decision in the final rule to transition the new clinical labor data over a four-year period will help to dampen both the positive and negative impacts of this new data. While the proposed rule estimated that aggregate impact of all final rule policies would range from -9% to +10%, the actual impact of the final rule ranges from -5% to +6%.

Impact of Proposed Changes by Selected Specialties

Specialty	Allowed Charges (mil)	Impact of work RVU Changes	Impact of PE RVU Changes	Impact of Malpractice RVU Changes	Combined Impact
Diagnostic Testing Facility	$664	0%	6%	0%	6%

Specialty	Allowed Charges (mil)	Impact of work RVU Changes	Impact of PE RVU Changes	Impact of Malpractice RVU Changes	Combined Impact
Portable X-Ray Supplier	$83	0%	2%	0%	2%
Hand Surgery	$214	0%	1%	0%	1%
Oral/Maxillofacial Surgery	$70	0%	-1%	0%	-1%
Vascular Surgery	$1,107	0%	-5%	0%	-5%
Interventional Radiology	$465	0%	-5%	0%	-5%

**Note: Combined impact may not equal the sum of work, PE and malpractice as a result of rounding. The diagnostic testing facility update seems somewhat puzzling in that the clinical labor data impact for this specialty was negative.*
Source: Table 136, CY 2022 Final PFS, display copy

Practice Expense

PE inputs for equipment, supplies and clinical labor (called direct PE inputs) are used as the first step in a multi-step calculation to generate PE RVUs. Direct PE inputs account for approximately 12% of PFS payments.

Key Takeaway: CMS finalized its proposal to update underlying rate data for clinical labor.
In conjunction with this final year of the supply and equipment pricing update, CMS finalized with modification its proposal to update clinical labor pricing data by transitioning to the new data over a four-year period starting in CY 2022. The original proposal did not include a four-year transition period. CMS will use data from the US Bureau of Labor Statistics and a methodology outlined in statute (66 FR 55257). This data was last updated in 2002. CMS finalized this proposal to address the issue of potential distortions in the allocation of direct PE that would result from updating the supply and equipment pricing without updating the clinical labor pricing. While the new data updated and increased the price of clinical labor inputs for physician services, the increased spending triggered negative adjustments to PE RVUs for many services in order to maintain budget neutrality.

Table 13 of the final rule summarizes the impact of the new data by specialty. In the first year of the four-year update, the impact ranges from -2% for Interventional Radiology and Diagnostic Testing Facilities to 2% for Portable X-Ray Suppliers. The impact on individual codes will vary. As noted previously, specialties with substantially higher average shares of direct costs attributable to clinical labor are anticipated to see increases in payment from the updated clinical labor pricing, and those with lower average proportions of PE attributable to clinical labor are anticipated to see decreases in payment.

The clinical labor data that CMS currently uses to calculate PE RVUs is almost 20 years old, but the policy to update this data was not without controversy. A coalition of office-based providers urged CMS not to finalize the policy because of the negative financial impact it will have on select specialties. A group of 73 House members, led by Reps. Bobby L. Rush (D-IL) and Gus Bilirakis (R-FL), also submitted a letter to CMS urging the agency not to update the clinical labor data.

Key Takeaway: CMS continues to update pricing for supplies and equipment.

CMS finalized that CY 2022 will be the final year of a four-year transition to updated pricing data for supplies and equipment, which means that PE input pricing for the affected items in 2022 will be based on 100% of the new pricing. The impact of this policy has varied across codes in the Medicare PFS. During this transition to new data, stakeholders have closely monitored its impact on PE RVUs and engaged with CMS by submitting comments, providing invoices and meeting directly with the agency. The incorporation of updated data is part of the agency's strategy to use the most current and accurate data to value PE RVUs.

Although CMS will have completed this four-year transition to new pricing data for supplies and equipment in 2022, it still lacks a process to update pricing for supplies and equipment on a regular and ongoing basis. CMS continues to accept invoices on an annual basis (to be submitted by early February of each year) to support updates to input pricing.

Key Takeaway: CMS continues to study how to price innovative technologies such as artificial intelligence.

CMS is increasingly encountering new services that incorporate artificial/augmented intelligence (AI) or software algorithms. This technology does not fit well into the current standard methodology for pricing resource costs in the development of PE RVUs. In the proposed rule, the agency sought guidance from stakeholders on how to incorporate these new technologies into PE payments, and in the final rule, CMS summarized the comments it received. Comments were wide-ranging, but many noted that the cost and impact of AI technologies varies across providers and systems, and is dependent on the clinical encounter. Many commenters noted that AI is not a replacement for physician work.

As the market for AI and other novel technologies in the healthcare space grows, such technologies may become a larger component of the Medicare PFS. CMS will continue to review the comments it received on this subject and will determine how best to continue engaging with stakeholders on this topic through future rulemaking.

Telehealth and Other Remote Services

Expanded flexibility for telehealth services during the PHE has led to an uptick in the use of telehealth, remote patient monitoring and communication-technology-based services.

Key Takeaway: CMS extended coverage for services added to the Medicare Telehealth List during the PHE through CY 2023, extends Category 3 status to additional codes, and finalized policies to increase access to mental health services.

During the COVID-19 PHE, the US Department of Health and Human Services (HHS) issued several waivers that made it easier to provide telehealth services to Medicare beneficiaries. These waivers, which are tied to the PHE, provide flexibility regarding where telehealth can be provided (*e.g.*, at home), which services can be provided (*e.g.*, expanded list of covered services), what type of technology can be used (*e.g.*, enforcement discretion around HIPAA requirements for two-way communication systems) and the level of payment for these services (*e.g.*, allowing the higher non-facility rate for office-based physicians). As a result, use of telehealth services has increased dramatically during the PHE. Providers, patients and other stakeholders who have urged Congress and CMS to allow

continued access to telehealth services by maintaining these flexibilities after the PHE ends, have been highly anticipating the agency's telehealth policies.

In this final rule, CMS added and extended coverage for certain telehealth services through CY 2023. This temporary extension will allow the agency to collect more data to inform the structure of telehealth coverage in a post-COVID-19 environment. As demand for telehealth beyond the pandemic has grown, CMS has placed a priority on determining which services can be appropriately provided via telehealth from a clinical perspective, and on addressing fraud and abuse concerns. According to CMS, COVID-19 has demonstrated that expanded telehealth policies may also help address access disparities among different populations.

Key telehealth proposals finalized in this rule are outlined below.

Proposal	Details
Extending Temporary Additions to Medicare Telehealth List Through CY 2023	In the CY 2021 final rule, CMS provided coverage through the end of the PHE for more than 100 services added to the Medicare Telehealth List on an interim basis. These services were given Category 3 status (Categories 1 and 2 represent the long-term criteria for additions to the telehealth list; Category 3 was created to allow additions not clearly fitting under Categories 1 and 2). **Final Policy**: In the CY 2022 final rule, CMS finalized as proposed the revised timeframe for inclusion of the services added to the Medicare telehealth services list on a temporary, Category 3 basis—retaining all services added to the Medicare telehealth services list on a Category 3 basis through CY 2023.
Extending Category 3 Status to Certain Codes	Certain codes were added to the Medicare Telehealth List on an interim basis but were not granted Category 3 status in the CY 2021 final rule. CMS solicited comments on whether these codes should be granted Category 3 status. **Final Policy**: In the CY 2022 final rule, CMS added CPT codes 93797 and 93798 (outpatient cardiac rehabilitation) and HCPCS codes G0422 and G0423 (intensive cardiac rehabilitation) to the Category 3 Medicare Telehealth Services List. As noted above, these Category 3 services are extended through CY 2023.
No Permanent Additions to Medicare Telehealth List	The agency uses the PFS rule process to update its telehealth list on an annual basis. Proposed permanent additions are based on nominations from stakeholders. **Final Policy**: While CMS received several nominations for this cycle, it declined to add any codes. In the final rule, CMS indicates that it does not believe any of the nominated codes (listed in Table 15) meet the criteria to be permanently added to the Medicare Telehealth Services List (under Categories 1 or 2).

Proposal	Details
Expanding Access to Mental Health Services	**Final Policy**: The final rule adopts multiple proposals to expand access for the treatment of mental health disorders. Of particular focus is increasing access to behavioral health services in rural or other underserved areas. **Final Policy**: CMS will allow payment for certain mental health services that are provided using audio-only technology for patients at home if certain conditions are met. Practitioners will be required to have the capacity to furnish two-way audio/video telehealth services, but may provide mental health services via audio-only in response to patient access issues or patient preference. **Final Policy**: CMS will cover mental health visits when they are provided by Rural Health Clinics and Federally Qualified Health Centers via interactive technology until the PHE ends. **Final Policy**: CMS will allow patients to receive mental health treatment services via telehealth from home, subject to certain requirements.* In the final rule, CMS broadly defines the "home" to include temporary lodging (such as hotels and homeless shelters) and locations that are a short distance from the beneficiary's home. **Final Policy**: CMS previously proposed that a beneficiary must see his provider in-person every six months to continue the mental telehealth treatment. In response to comments emphasizing the importance of mental health accessibility and the lack of mental health providers, CMS instead finalized a 12-month continuing in-person requirement. Combining the statutory requirement and the CMS requirement, a beneficiary must have seen her provider in-person within the six-month period prior to starting mental telehealth treatment, and generally must subsequently see her provider in 12-month intervals for continuing treatment. CMS also established criteria for an exception to its in-person annual visit requirement, including situations in which the risks and burdens associated with an in-person service may outweigh the benefit. *The CAA of 2021 permits Medicare beneficiaries to access telehealth treatment for a broader range of mental health conditions from a broader range of qualifying locations, including the beneficiary's home, after the PHE. However, the CAA imposes an in-person requirement, requiring the beneficiary to have an in-person visit with her provider within the six months

Proposal	Details
	prior to initiation of the mental telehealth treatment. The CAA of 2021 also gives the HHS Secretary authority to impose additional in-person requirements, as appropriate, for subsequent mental telehealth treatment.
New Originating Site	**Final Policy**: Effective CY 2023, Rural Emergency Hospitals will qualify as a telehealth originating site.* *Required by CAA of 2021
Permanently Adopting Virtual Check-In Code	The CY 2021 final rule established, on an interim basis, code G2252 for an extended virtual check-in (11-20 minutes), which could be furnished using any form of synchronous communication technology, including audio-only. CMS established a payment rate of 0.50 work RVUs. **Final Policy**: In the CY 2022 final rule, CMS permanently adopted coding and payment for code G2252, as proposed.

While the final rule temporarily extends coverage for certain telehealth services, congressional action is required to waive originating site and geographic requirements and to allow telehealth to be provided at home after the PHE ends. Many stakeholders are advocating for continued access to telehealth services beyond the PHE, and the issue has received some support in Congress. For example, Senators Bill Cassidy, MD (R-LA), Tina Smith (D-MN), John Thune (R-SD) and Ben Cardin (D-MD) introduced the bipartisan Telemental Health Care Access Act of 2021 to repeal the in-person requirement for mental telehealth services provided at home.

Key Takeaway: CMS finalized the adoption of remote treatment management (RTM) codes and their valuation for CY 2022 but remained silent on remote physiologic monitoring (RPM) policy proposals, despite utilization growth in 2020

In recent years, CMS established payment for several RPM codes, which generated significant stakeholder interest prior to the pandemic. During the PHE, CMS implemented flexibilities to allow for broader use of these services but provided limited guidance on how they should be reported. Industry stakeholders expected a significant increase in use of these codes in CY 2020 and anticipated that CMS might propose additional policies to clarify and potentially limit the use of these codes. In previous rulemaking, CMS clarified that the RPM codes are eligible for billing only by healthcare practitioners who may bill for evaluation and management services.

While utilization for some RPM codes increased more than five-fold, CMS did not propose any policy changes specific to the RPM codes. Several questions therefore remain regarding these codes:

- How will CMS operationalize the specific requirements for these codes?
- Will CMS require specific details to be submitted with the claim, or will it be handled by claims audits?
- Will there be limitations on the types of devices that can be used or the types of physiological parameters that will be covered under these codes?

Some providers and medical device manufacturers and suppliers will welcome the lack of additional restrictions as they seek to expand use of these services in the absence of any applicable local coverage determinations.

In the final rule, CMS did introduce new remote treatment management (RTM) codes (98975-98977, 98980-98981) that are effective January 1, 2022. In the proposed rule, CMS expressed concerns regarding the construct of a subset of these RTM codes and whether they could be billed (as intended) by a subset of practitioners (including physical and occupational therapists as well as speech language pathologists) outside the context of billing for incident-to services of a healthcare practitioner. After seeking feedback from stakeholders, and despite ongoing concerns regarding the code construction, CMS adopted these RTM codes and established national payment rates. This policy was based on CMS's decision to ensure beneficiary access. CMS expects ongoing discussions on the RTM codes and addressing outstanding concerns in the coming year.

Payment for Services Provided by Physical Therapy Assistants and Occupational Therapy Assistants

Key Takeaway: Services provided by physical therapy assistants and occupational therapy assistants will be paid at 85%, as required by statute.

In this final rule, CMS implemented section 53107 of the Bipartisan Budget Act of 2018. This legislation requires CMS to pay 85% of the otherwise applicable Part B payment amount for physical therapy and occupational therapy services furnished in whole or in part by physical therapy assistants and occupational therapy assistants (when they are appropriately supervised by a physical therapist or occupational therapist, respectively) for dates of service on and after January 1, 2022. CMS will use new modifiers (CQ and CO) to identify and make payment at 85%.

CMS also identified certain limited circumstances in which the CQ/CO modifier would not need to be billed.

COVID-19 Vaccine Administration

Key Takeaway: Enhanced payments for COVID-19 vaccine administration will continue through CY 2022.

CMS finalized a policy to continue enhanced payment for COVID-19 vaccine administration. CMS will maintain the current payment rate of $40 per dose for administration of the COVID-19 vaccines through the end of the calendar year in which the PHE ends. Effective January 1 of the year following the year in which the PHE ends, the payment rate for COVID-19 vaccine administration will align with the payment rate for the administration of other Part B preventive vaccines, which is currently $30 per dose.

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

Key Takeaway: CMS implemented a statutory change to reduce patient financial burden for screening.

Medicare beneficiaries do not need to meet a deductible or pay the standard Part B coinsurance amount for a screening colonoscopy or sigmoidoscopy. However, in the past, if a polyp or other lesion was detected on a screening evaluation and removed, then the procedure was not to be billed as a screening but rather as a diagnostic procedure, subject to standard co-insurance requirements.

Following a statutory change in the CAA, CMS finalized two regulatory changes that will reduce the financial burden of colorectal cancer screening to beneficiaries. Beginning January 1, 2022, screening colonoscopies and sigmoidoscopies that detect a lesion and lead to tissue removal will be treated as screening rather than diagnostic procedures and will be subject to special screening payment provisions. CMS also finalized its proposal to phase in a reduction in beneficiary co-insurance requirements between 2022 and 2030, at which point beneficiary co-insurance will be zero.

Providers and patients have been urging CMS and Congress for years to address the unexpected payment burden for patients who have screening colonoscopies that turn into diagnostic procedures after the start of the procedure. While many stakeholders welcome these policy changes, some are disappointed that the beneficiary co-insurance will not be fully eliminated until 2030.

Billing for Physician Assistant Services

Key Takeaway: CMS amended regulations to allow physician assistants (PAs) to directly bill Medicare.

Non-physician practitioners, including nurse practitioners, clinical nurse specialists and PAs, may provide physician services (as defined by the Social Security Act) under Medicare and receive a reimbursement rate of 85% of the PFS payment rate. Statutory restrictions previously have prohibited PAs (but not the other types of non-physician practitioners) from billing Medicare for services directly. Instead, a physician employer was required to bill for PA services.

The 2021 CAA permits PAs to directly bill Medicare effective in 2022. In this final rule, CMS implemented regulatory changes to conform to the statutory change.

CMS anticipates that this change, for which the PA community has long advocated, will expand access to care and reduce administrative burden on PA practices.

Potentially Misvalued Codes

Key Takeaway: CMS identified CPT© code 49436 (Delayed creation of exit site from embedded subcutaneous segment of intraperitoneal cannula or catheter) as a potentially misvalued code.

The Affordable Care Act mandates regular review of fee schedule rates for physician services paid by Medicare, including services that have experienced high growth rates. CMS established the potentially

misvalued code process to meet this mandate. Codes that are identified for review under this process may eventually have their values increased, decreased or maintained. The risk of reduced values is often a concern for stakeholders when a services is proposed for evaluation under the potentially misvalued code process.

CPT code 49436 (*Delayed creation of exit site from embedded subcutaneous segment of intraperitoneal cannula or catheter*) is currently not priced in the office. A commenter provided information indicating that the procedure could safely be performed in the office setting and would be less costly in such a setting. CMS also received information suggesting that a non-facility/office setting would be less burdensome and potentially safer for patients and providers during the PHE. Because the typical site of service may need to change, CMS finalized CPT 49436 as a potentially misvalued code for CY 2022.

In the CY 2022 PFS proposed rule, CMS noted that while the public had nominated additional codes for review, CMS declined to identify them as potentially misvalued. CMS did propose CPT code 59200 (*Insertion of cervical dilator (e.g., laminaria, prostaglandin) (separate procedure*)) as potentially misvalued, but based on information received during the comment period, CMS did not finalize this proposal. The agency had noted that the PE inputs for 59200 did not include one of the appropriate supply items, Dilapan-S. However, most commenters noted that an alternative to Dilapan-S, a laminaria tent, is already included as a PE and is much less costly. The agency did not find enough evidence that Dilapan-S was "widely used as a replacement" or "in any other way a better performing supply," and accordingly did not finalize CPT 59200 as a potentially misvalued code.

Quality Payment Program

Under the QPP, eligible clinicians may elect to be subject to payment adjustments based upon performance under MIPS, or to participate in the Advanced Alternative Payment Model (APM) track. Eligible clinicians choosing the MIPS pathway will have payments increased, maintained or decreased based on relative performance in four categories: quality, cost, promoting interoperability and improvement activities. Eligible clinicians choosing the APM pathway will automatically receive a bonus payment once they meet the qualifications for that track.

QPP: MIPS

Key Takeaway: CMS will launch the MIPS Value Pathways (MVPs) in 2023.

CMS finalized a proposal to launch the MVPs in 2023. In CY 2021, CMS delayed implementation of the MVPs until the 2022 performance period or later. The MVPs are a voluntary participation option to motivate clinicians to move away from reporting on self-selected activities and measures (Traditional MIPS) and towards an aligned set of measure options designed to be meaningful to patient care and more relevant to a clinician's scope of practice. In this rule, the agency set an implementation timeline, defined MVP criteria and finalized the first set of MVPs for performance year 2023.

- MVP Implementation Timeline: The MVP program will begin in CY 2023.
- MVP Criteria: MVPs must include at least one outcome measure, or one high-priority measure relevant to each specialty participating in the MVP in instances when an outcome measure is not available. Any Qualified Clinical Data Registry measures must be fully tested.
- MVP Participation Options: For the 2023, 2024 and 2025 performance years, CMS will allow individual clinicians, single specialty groups, multispecialty groups, subgroups and APM entities

to report MVPs. Beginning in the 2026 performance year, multispecialty groups will be required to form subgroups in order to report MVPs.

- 2023 MVPs: For the CY 2023 performance year, CMS established seven MVPs (Rheumatology, Stroke Care and Prevention, Heart Disease, Chronic Disease Management, Emergency Medicine, Lower Extremity Joint Repair and Anesthesia).

In the proposed rule, CMS considered the sunset of Traditional MIPS at the end of the CY 2027 MIPS performance period. In the final rule, CMS indicated that while it continues to consider when to sunset traditional MIPS, any sunset proposal will be made in future rulemaking. Over the years, participation in traditional MIPS has been criticized as expensive and time consuming with low positive payment adjustments as a reward, and as having an uncertain impact on patient care. At the same time, some stakeholders raised concerns about sunsetting MIPS because MVPs are as yet untested and it is unclear whether there will be MVP options for all participants.

Key Takeaway: CMS increased the threshold to avoid MIPS negative payment adjustments.

The MIPS performance threshold for the 2022 performance year is 75 points. This represents an increase of 15 points from the 2021 MIPS performance threshold. To avoid a negative adjustment in the 2024 payment year, providers' MIPS Total Score must reach this performance threshold in 2022. The 2022 MIPS performance threshold was set by using the mean score from the 2017 performance year. CMS is required by statute to base the MIPS performance threshold on the mean or median of a previous year. While the increase is in line with increases from previous years, this is the first time that CMS has based the performance threshold on a previous year's score. Previously CMS has set the performance threshold artificially. An additional performance threshold is set at 89 points for an exceptional performance adjustment. Performance year 2022 is the final year for the exceptional performance adjustment.

This increased performance threshold is expected to reduce the number of clinicians eligible for a positive payment adjustment. Because the budget neutral nature of MIPS requires negative payment adjustments to fund the positive payment adjustments, the agency anticipates that clinicians earning positive payment adjustments may see modest increases in their payment adjustments, which historically have been significantly less than allowed by statute. For example, while the 2021 MIPS payment adjustments were set at +/-7% by statute, actual payment adjustments varied between -7% and +1.79%.

Changes to MIPS 2022 Performance Categories and Weights

CMS finalized proposals to update the measures and other policies for the various performance categories:

- Quality: Reduction from 209 measures in 2021 to 200 in 2022 (removal of 13 and addition of four), plus modifications to 87 existing measures and changes to specialty sets
- Cost: Addition of five episode-based cost measures
- Improvement Activities: Addition of seven new improvement activities, removal of six and modification of 15
- Promoting Interoperability: Revisions to reporting requirements, including addition of new measures.

The 2022 MIPS performance category weights, which are specified in statute, are summarized below.

Performance Category	PY* 2021 Weight	PY* 2022 Final Weight	Percent Change
Quality	40%	30%	-10%
Cost	20%	30%	+10%
Promoting Interoperability	25%	25%	0%
Improvement Activities	15%	15%	0%

*PY=Performance Year

Note that those participating in Traditional MIPS as an APM entity or in the APM Performance Pathway as an individual, group or APM entity will have different scoring weights than those described above.

MIPS Participation Expanded

For 2022, CMS expanded the definition of MIPS eligible clinicians to include clinical social workers and certified nurse midwives.

Complex Patient Bonus Extended

Because of the expected continued impact of COVID-19, CMS will continue to double the complex patient bonus (capped at 10 points) through 2022. The bonus was implemented in 2021 and is applied to the MIPS Total Score.

Medicare Shared Savings Program

Key Takeaway: CMS finalized the extended phase-in of quality performance requirements.

In the CY 2021 PFS final rule, CMS finalized numerous policies related to accountable care organization (ACO) quality performance reporting and measurement. For 2022, ACOs originally would have been required to actively report quality data on three electronic clinical quality measures/MIPS clinical quality measures (eCQM/MIPS CQM) and field the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey. CMS would have calculated two measures using administrative claims data. The six measures would have been included in the calculation of the ACO's quality performance score for purposes of the Medicare Shared Savings Program. In response to stakeholder pushback, CMS finalized an additional delay of these requirements.

Under the final rule, CMS will extend the use of the CMS Web Interface as a collection type for performance years 2022, 2023 and 2024 for Shared Savings Program ACOs (one year longer than proposed). The CMS Web Interface will be unavailable beginning in 2025. CMS did not finalize the proposed requirement that ACOs report at least one eCQM/MIPS CQM in performance year 2023 to meet the quality performance standard. CMS set out the ACO reporting requirements for 2022 and subsequent performance years, giving ACOs an additional year to transition to the new system. Beginning in 2025, ACOs will be required to report the three eCQMs/MIPS CQMs and administer a CAHPS for MIPS survey, and CMS will calculate two claims-based measures included in the APM Performance Pathway. If an ACO does not report the measures and does not administer the survey, the ACO will not meet the quality performance standard.

CMS also proposes to freeze the quality performance standard at the 30th percentile MIPS quality performance category score and provide an incentive for ACOs to report eCQM/MIPS CQM in PY 2022 and 2023. In PY 2024, the threshold for quality performance standard would increase to the 40th percentile across all MIPS quality performance category scores.

The final rule also contains technical changes to the Medicare Shared Savings Program. The rule summarizes comments received related to benchmarking and risk adjustment, but the agency declined to act on these policies in the final rule, to the disappointment of some stakeholders.

Advanced APM Track

Key Takeaway: The final rule codifies the CAA provision to freeze Advanced APM thresholds at 2020 levels.

Statute sets specific revenue and patient count thresholds that APMs are required to meet to qualify for their 5% advanced APM bonus payment. The thresholds were slated to dramatically increase in 2021 for the 2023 bonus payment, but the CAA of 2021 held the thresholds at the 2020 levels for two years. The final rule implements this statutory change. Under the new provision, the thresholds remain at 50% for the payment method and 35% for the patient count method for 2023 and 2024 payment years (2021 and 2022 performance years). Absent congressional action, the 2022 performance year is the last year of the advanced APM bonus.

Removal of National Coverage Determinations

Key Takeaway: CMS retired two national coverage determinations (NCDs).

In the proposed rule, CMS sought comments on its proposal to withdraw two NCDs. In the final rule CMS finalized this proposal, removing one NCD that provides limited coverage and one non-coverage NCD. CMS believes that these NCDs no longer contain pertinent or clinically relevant information and are rarely used by beneficiaries. Services that were automatically covered under these NCDs would now be covered at the Medicare Administrative Contractor's (MAC's) discretion, and coverage of services that were previously barred by the NCDs is also at the MAC's discretion. CMS believes this change will result in greater contractor flexibility and will better serve the needs of Medicare beneficiaries.

NCD 180.2 provides limited coverage of enteral and parenteral nutrition products. CMS decided to retire this NCD, noting that proposed local coverage determinations on enteral and parenteral nutrition under the Durable Medical Equipment MACs, if finalized, will continue to provide limited coverage of these services.

NCD 220.6 non-covers PET imaging unless a PET imaging technique and indication is expressly covered under other subsections of the NCD. Currently, MACs have the discretion to cover PET using radiopharmaceuticals for their US Food and Drug Administration approved labeled indications for oncologic imaging. However, PET imaging for non-oncologic uses is non-covered by NCD 220.6 unless another subsection NCD (NCDs 220.6.1 – 220.6.20) expressly covers the service. CMS finalized the removal of NCD 220.6, effectively giving discretion to local contractors to decide on PET imaging not expressly addressed by NCDs 220.6.1 – 220.6.20.

Determination of Average Sales Price for Certain Self-Administered Drug Products

Key Takeaway: CMS implements legislative provision to control the price impact of self-administered drugs on Medicare Part B payments.

Drugs eligible for payment under Medicare Part B are generally reimbursed based on a statutory formula of 106% of the drug's average sales price (not accounting for any effects of sequestration). Generally, drugs reimbursed under Medicare Part B are not self-administered drugs. However, multiple formulations of a drug assigned different national drug codes may have prices crosswalked to an HCPCS code to which a price is assigned. When one or more of the formulations of a drug crosswalked to a HCPCS code are marketed as self-administered formulations, then the price of the self-administered drug that is not reimbursed by Medicare Part B (which may be covered by Medicare Part D prescription drug plans) can impact the price of the drug under Medicare Part B. This could result in a provider or supplier being paid substantially more than 106% of the drug's cost. The Office of Inspector General raised concerns that this could provide perverse economic incentives. The CAA of 2021 directed the Office of Inspector General to look for such drugs, report them to the secretary of HHS, and permit Medicare to make a payment rate determination that includes or excludes self-administered drug price data, based on whichever calculation provides the lower price. CMS finalized its proposed regulations to implement this authority.

Implementation of the Appropriate Use Criteria Program

Key Takeaway: CMS finalized its policy to delay the payment penalty phase of the Appropriate Use Criteria (AUC) program until January 1, 2023, at the earliest.

The Protecting Access to Medicare Act of 2014, Section 218(b), established the AUC program. Under this program, a practitioner who orders an advanced diagnostic imaging service for a Medicare beneficiary in an applicable setting is required to consult an AUC using a qualified clinical decision support mechanism. The practitioner furnishing the imaging service must report the AUC consultation information on the Medicare claim.

In the CY 2018 rulemaking cycle, CMS established January 1, 2020, as the effective date for the program, with the first year serving as the operations and education testing period. In July 2020, in response to the COVID-19 PHE, CMS extended the testing period an additional year.

In this final rule, CMS delayed (as proposed) the penalty period effective date until January 1, 2023, or January of the year following the end of the PHE. During the penalty period, any claims that do not meet the program requirements will be denied or rejected. In addition to the delayed penalty phase, CMS discussed and finalized solutions for several issues and special circumstances identified during the testing period thus far. CMS also reiterated that the COVID-19 PHE qualifies as extreme and uncontrollable circumstances (EUC), and practitioners experiencing a hardship due to the PHE can attest for an EUC hardship exemption.

Acknowledging the impact of the COVID-19 PHE and the time required to implement any operational changes to CMS's claims processing system, CMS sought to give stakeholders ample time to prepare for the upcoming penalty phase.

Payment for Synthetic Skin Substitutes

Key Takeaway: CMS finalized its policy to reimburse 10 Unique synthetic skin substitute products separately from procedure.

CMS finalized the creation of HCPCS code C1849 in the 2021 Hospital Outpatient Prospective Payment System (OPPS) to reimburse application of synthetic skin substitutes in the outpatient hospital setting, but did not provide a reimbursement mechanism for the provision of synthetic skin substitutes in a physician's office or other non-institutional setting. During the 2021 OPPS rulemaking process, commenters requested that CMS create product-specific HCPCS codes to facilitate reimbursement more closely tied to the costs of individual products, but CMS created only a single code.

For 2022, CMS proposed the creation of eight new HCPCS codes to describe application of synthetic skin substitutes that would treat the cost of the skin substitute as a supply cost of a physician service. The proposed codes do not distinguish between specific products, establishing a single cost for all synthetic skin substitutes.

The approach to reimburse the cost of drugs and biologicals as part of a physician service has a recent precedent. In the 2020 PFS, CMS created two HCPCS codes for the administration of intranasal esketamine, a self-administered drug. This decision provided a reimbursement pathway for a drug not otherwise reimbursable under Medicare Part B, but also created a precedent of reimbursing a drug as PE reimbursed as part of a physician's service, which is not subject to use of the average sales price +6% formula or product-specific price determinations.

In the final rule, in response to commenter feedback, CMS stated that it will establish unique HCPCS Level II codes for 10 products for which CMS received HCPCS Level II coding applications. CMS received the applications for these 10 products over the course of several quarterly and biannual coding cycles in 2020 and 2021. The 10 products are NovoSorb SynPath, Restrata Wound Matrix, Symphony, InnovaMatrix AC, Mirragen Advanced Wound Matrix, bio-ConneKt Wound Matrix, TheraGenesis, XCelliStem, Microlyte Matrix and Apis. CMS noted that its decision regarding these 10 products is part of ongoing review of HCPCS coding approaches for a broad range of skin substitute products.

CMS also finalized that these products will be payable in the physician office setting as contractor priced products that are billed separately from their application procedure. These HCPCS Level II codes may be billed as add-on codes to the appropriate existing surgical application codes (CPT codes 15271-15278). CMS will post information about these new HCPCS Level II codes on its website in November 2021. CMS also stated that it will consider the recommendation to allow for payment of skin substitute application add-on codes under the OPPS as a part of CMS's ongoing review of all skin substitutes.

Health Equity Initiative

As part of the Biden Administration's commitment to advancing health equity and the Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, CMS has issued requests for information and proposed health equity initiatives in recent rules, including the CY 2022 PFS proposed rule. CMS solicited comments on how to improve the collection and utility of data around health disparities that arise from social risk factors, including race

and ethnicity. CMS indicated in this final rule that it will use the comments to inform ongoing health equity efforts.

Conclusion

The final rule establishes Medicare payment policies for physicians in CY 2022, but great uncertainty about the coming year remains. Any potential congressional action to avert physician payment cuts is not expected until the end of 2021. Even if Congress acts, these cuts may only be mitigated, not completely eliminated. The COVID-19 pandemic also continues to impact physician practices. The ongoing uncertainty regarding how the pandemic will evolve over the next few months creates another set of challenges. During the pandemic, physician practices have relied on many of the flexibilities authorized by HHS which are tied to the PHE. The PHE is currently extended until January 16, 2022.

As the year comes to a close, the physician community and other healthcare stakeholders will closely monitor Congress, to see if it will address physician payment cuts, and the Administration, to see if it will continue to extend flexibilities tied to the PHE through 2022.

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This summary does not address several topics included in the final rule, including but not limited to the expansion of the Medicare Diabetes Prevention Program and a policy regarding a proposed framework for consideration of 505(b)(2) drugs for payment purposes.