Policy Update

CMS Releases CY 2022 Physician Fee Schedule Proposed Rule

On July 13, 2021, the Centers for Medicare & Medicaid Services (CMS) released the CY 2022 Revisions to Payment Policies under the Physician Fee Schedule (PFS) and Other Changes to Part B Payment Policies [CMS-1751-P] Proposed Rule, which includes proposals related to Medicare physician payment and the Quality Payment Program (QPP). Because Biden Administration CMS health officials were appointed late in the rulemaking cycle, the rule includes no sweeping policy proposals like the evaluation and management payment changes included the CY 2021 PFS proposed rule. This year's proposed rule does include significant policy proposals addressing telehealth and other COVID-19 flexibilities, updates to the underlying practice expense data that will impact payment rates, policies promoting health equity, and enhancements and other changes to further develop physician quality initiatives.

Key takeaways from the CY 2022 PFS Proposed Rule:

- 2022 proposed physician conversion factor (CF) of $33.5848, representing a 3.75% reduction from the 2021 CF of $34.8931
- Extension of coverage to the end of CY 2023 for services temporarily added to the Medicare Telehealth Services List during the pandemic
- Update to underlying clinical labor cost data that may have a disproportionate positive impact on certain specialties with higher-than-average share of labor costs
- Health equity data collection initiative designed to give providers a more comprehensive understanding of health disparities impacting their patients
- Timeline to sunset the Traditional Merit-based Incentive Payment System (MIPS) by end of 2027

Comments on the proposed rule are due on September 13, 2021.

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

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

PFS Major Proposals

Conversion Factor

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

Key Takeaway: CY 2022 CF Would Decrease to $33.5848, a Reduction of 3.75%

Medicare Physician Conversion Factor (2017–2021)		
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	**33.5848**	**-3.75**

The 2022 proposed physician CF is $33.5848. This represents a decrease of 3.75% from the 2021 CF of $34.8931. The proposed 2022 anesthesia CF is $21.0442, in comparison to the 2021 CF of $21.5600, representing a decrease of 2.39%.

The proposed update is based on two factors: there is a 0% update scheduled for the PFS in CY 2022[1], and a funding patch passed by Congress at the end of CY 2020 is only funded through the end of CY 2021. Signed into law on December 27, 2020, 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.

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, and statutory sequestration cuts required by pay-as-you-go legislation, which were triggered by the significant additional spending in the American Rescue Plan enacted in March 2021.

These payment reductions come at a time when physician practices, hospitals that employ physicians and other stakeholders are facing uncertainty about the future of their pandemic recovery including what flexibilities for telehealth services may continue beyond the public health emergency (PHE), and are 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 likely will continue to press Congress for relief from these payment cuts.

[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.

Specialty Impact

Key Takeaway: Impact by Specialty Ranges from -9% to +10%

Actual payment rates are affected by a range of proposed policy changes related to physician work, PE and malpractice RVUs. CMS summarizes the aggregate impact of these changes in Table 123 in the proposed rule. While impact on individual practices will vary based on service mix, the table provides insight into the overall impact of the policies in the rule for a specific specialty. Specialty impacts range from -9% for interventional radiology to +10% for portable x-ray supplier.

While some of the differences in specialty impact result from proposed changes to individual procedures, the CMS proposal to update clinical labor pricing is anticipated to lead to significant decreases in payments for specialties with substantially lower average shares of direct costs attributable to labor. The proposal to update clinical labor pricing, which will impact PE RVUs, in combination with the continued phase-in of previously finalized updates to supply and equipment pricing, likely drive the negative impact for interventional radiology, vascular surgery, radiation oncology and oral/maxillofacial surgery summarized in the table below.

Specialties with substantially higher average shares of direct costs attributable to labor are anticipated to see significant increases in payment from the CMS proposal to update clinical labor pricing. Specialties anticipated to benefit from the proposal include portable x-ray, family practice and hand surgery, which rely primarily on clinical labor for their PE costs.

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
Portable X-Ray Supplier	$84	0%	10%	0%	10%
Family Practice	$5,725	0%	2%	0%	2%
Hand Surgery	$222	0%	2%	0%	2%
Oral/Maxillofacial Surgery	$70	0%	-4%	0%	-4%
Radiation Oncology And Radiation Therapy Centers	$1,660	0%	-5%	0%	-5%
Vascular Surgery	$1,144	0%	-8%	0%	-8%
Interventional Radiology	$480	0%	-9%	0%	-9%

**Note: Combined impact may not equal the sum of work, PE and malpractice as a result of rounding.*
Source: Table 123, CY 2022 Proposed PFS, display copy

Practice Expense

Key Takeaway: CMS Continues to Update Pricing for Supplies and Equipment

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.

CY 2022 is the fourth and 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 these data is part of the agency's strategy to use the most current and accurate data to value PE RVUs. Although CMS has completed this four-year transition to new data, 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 Proposes to Update Underlying Rate Data for Clinical Labor

In conjunction with this final year of the supply and equipment pricing update, CMS proposes an update to the CY 2022 clinical labor pricing, using 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 proposed this update 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.

Table 6 of the proposed rule summarizes the impact of the new data by specialty. The impact ranges from -6% for Diagnostic Testing Facility to +10% for Portable X-ray Supplier. The impact on individual codes will vary. As noted above, specialties with substantially higher average shares of direct costs attributable to clinical labor are anticipated to see significant increases in payment from the CMS proposal to update clinical labor pricing, and those with lower average proportions of practice expense attributable to clinical labor are anticipated to see decreases in payment.

Key Takeaway: CMS Solicits Comments on Pricing of Innovative Technologies Such as Artificial Intelligence

CMS is increasingly encountering new services that have artificial/augmented intelligence (AI) or software algorithms incorporated. This technology does not fit well into the current standard methodology for pricing resource costs in the development of PE RVUs, and the agency is seeking guidance from stakeholders. Specifically, the agency solicits comment regarding the use of innovative technologies, including but not limited to software algorithms and AI, and their effects on physician work intensity, cost structures and resource costs, quality of care and equity.

As the market for AI and other novel technologies in the healthcare space grows, this may become a growing component of the Medicare PFS.

Telehealth and Other Remote Services

A key change implemented during the pandemic was expanded flexibility for telehealth services, which has led to an uptick in the use of telehealth, remote patient monitoring and communication-technology-based services.

Key Takeaway: CMS Proposes Extension Through CY 2023 for Services Added to Telehealth List During the PHE and 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 related to 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 rules) and the level of payment for these services (*e.g.*, allowing the higher nonfacility rate for office-based physicians). Use of telehealth services increased dramatically during the PHE. Providers, patients and other stakeholders are urging Congress and CMS to allow continued access to telehealth services by maintaining these flexibilities after the PHE ends. In light of this focused attention on telehealth, the agency's telehealth proposals have been highly anticipated.

In this proposed rule, CMS proposes temporary extension of telehealth coverage for certain services through CY 2023. This temporary extension would 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. The agency has also indicated that COVID-19 has demonstrated that expanded telehealth policies may also help address access disparities.

Key telehealth proposals are outlined below.

Topic	Proposal
Temporary Additions to Medicare Telehealth List	Extension of 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). *In this rule, CMS proposes to extend coverage for these services through the end of CY 2023.*
Codes Not Granted Category 3 Status	CMS Solicits Comments on 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 PFS Final Rule. *In this rule, CMS solicits comments on whether these codes should be granted Category 3 status (Table 11 in CY 2022 PFS Proposed Rule).*

Topic	Proposal
Permanent Additions to Medicare Telehealth List	No Permanent Additions Proposed for Medicare Telehealth List The agency uses the PFS rule process to update its telehealth list on an annual basis. Proposed additions are based on nominations from stakeholders. *While CMS received several nominations for this cycle, it declined to propose any codes. In the proposed rule, CMS indicates that it does not believe any of the nominated codes meet the criteria to be permanently added to the Medicare Telehealth List (under Categories 1 or 2).*
Treatment of Mental Health Disorders	Expand Access to Treatment of Mental Health Services The proposed rule includes multiple proposals to expand access to the treatment of mental health disorders. Of particular focus is addressing the need for increased access to behavioral health services in rural or other underserved areas. *CMS proposes to allow patients to receive mental health treatment services via telehealth from home.** *CMS proposes to cover mental health visits when they are provided by Rural Health Clinics and Federally Qualified Health Centers via interactive technology.* *CMS proposes to allow payment for certain mental health services that are provided using audio-only technology for patients at home if certain conditions are met. Practitioners would be required to have the capacity to furnish two-way, audio/video telehealth services, but may providing mental health services via audio-only due to patient access or personal preference.* *Required by statute (CAA of 2021)
New Originating Site	Rural Emergency Hospital *Effective CY 2023, CMS proposes to establish Rural Emergency Hospitals as a telehealth originating site.** *Required by statute (CAA of 2021)
Virtual Check-In Code	Permanent Adoption of Code G2252 – Virtual Check-in The CY 2021 PFS 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.

Topic	Proposal
	CMS proposes to permanently adopt coding and payment for code G2252

While the proposed rule would temporarily extend coverage for certain services, once the PHE ends Congressional action is necessary to waive the telehealth origination requirement and allow telehealth to be provided at home. This is a critical flexibility advocated by stakeholders, and it has received some support in Congress.

Key Takeaway: CMS Issues No Major RPM Policy Proposals, Despite Utilization Growth in 2020

In recent years, CMS has established payment for several remote physiologic monitoring (RPM) codes. These codes had generated a significant level of 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 these services 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 further clarify and potentially limit the use of these codes.

While utilization for some of the RPM codes increased more than five-fold, CMS does not propose any policy changes specific to the RPM codes. CMS introduces the new remote treatment management (RTM) codes (989X1 – 989X5) that are effective January 1, 2022, and proposes payment rates for these new codes, similar to the RPM codes. The agency also seeks feedback from stakeholders on the types of devices that may be applicable for the RTM codes.

Several questions remain surrounding these RPM 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?

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

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

Key Takeaway: CMS Proposes to Implement Statutory Change to Reduce Patient Financial Burden for Screening

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

Following a statutory change in the CAA, CMS proposes to make two regulatory changes that will reduce the financial burden of colorectal cancer screening to beneficiaries. CMS proposes that 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 proposes to phase in a reduction in beneficiary co-insurance requirements between 2022 and 2030, at which point beneficiary co-insurance will be zero.

These policy changes would be welcomed by both providers and patients, who have been urging CMS and Congress for years to address the unexpected payment burden for patients who have screening colonoscopies that turn diagnostic.

Billing for Physician Assistant (PA) Services

Key Takeaway: CMS Proposes to Amend Regulations to Allow PAs to Directly Bill Medicare

Nonphysician practitioners (NPPs), including nurse practitioners, clinical nurse specialists and physician assistants, 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 have prohibited PAs (but not the other types of NPPs) from being able to bill Medicare for services directly, however; a physician employer was required to bill. The 2021 CAA permits PAs to directly bill Medicare effective in 2022, and CMS proposes regulatory changes to conform to the statutory change.

CMS anticipates that this change, 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 Solicits Comments on Potentially Misvalued Codes

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. In the CY 2022 proposed PFS, CMS noted that the following codes had been nominated for review by the public:

Code	Descriptor
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2
49436	Delayed creation of exit site from embedded subcutaneous segment of intraperitoneal cannula or catheter
55880	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance
59200	Insertion of cervical dilator (*e.g.*, laminaria, prostaglandin) (separate procedure)
66982	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (*e.g*, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg,

Code	Descriptor
	iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation
66986	Exchange of intraocular lens

CPT 59200 (insert cervical dilator PE supply) is the only code which CMS is proposing for review. The agency stated the PE inputs for 59200 did not include one of the necessary supply items. The agency stated that stakeholders did not make an adequate case for review of values for any of the other codes.

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 one of their services is proposed for revaluation under the Potentially Misvalued Code process.

Quality Payment Program

Under the QPP, eligible clinicians elect either to be subject to payment adjustments based upon performance under MIPS or they may elect 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 Proposes Timeline to Implement MVPs and Sunset Traditional MIPS
In CY 2021, CMS delayed the implementation of the MIPS Value Pathways (MVPs) until the 2022 performance period or later. The MVP is a voluntary participation option to motivate clinicians to move away from reporting on self-selected activities and measures, 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 proposed rule, the agency updates the MVP criteria, proposes an implementation timeline for MVPs, introduces the first set of proposed MVPs and sets a date to potentially sunset traditional MIPS.

The proposals described below are open for comment:

- MVP Criteria: Proposed updates to the MVP criteria include a requirement of at least one outcome measure, inclusion of one high priority measure relevant to each specialty participating in the MVP, and a requirement that any Qualified Clinical Data Registry measures must be fully tested.
- MVP Implementation Timeline: CMS proposes to initiate the MVP program in CY 2023, to provide time for MIPS eligible clinicians to familiarize themselves with MVPs and begin preparing their practices for participation (*e.g.*, system updates).
- Proposed MVPs: For the CY 2023 performance year, CMS proposes seven MVPs (Rheumatology, Stroke Care and Prevention, Heart Disease, Chronic Disease Management, Emergency Medicine, Lower Extremity Joint Repair and Anesthesia).
- Sunset of Traditional MIPS: CMS is proposing to sunset traditional MIPS at the end of the 2027 performance and data submission periods.

Over the years, Traditional MIPS has been criticized as being expensive and time consuming with low positive payment adjustments as a reward, and an uncertainty regarding its impact on patient care. At the same time, some stakeholders may raise concerns about the proposal to sunset traditional MIPS because MVPs are as yet untested, and it is unclear whether there will be MVP options for all participants. While the proposed sunset is still years away, stakeholders may urge CMS to provide further details on the transition process.

Key Takeaway: CMS Proposes Increased Threshold to Avoid MIPS Negative Payment Adjustments

The proposed 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. 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 CMS is basing the performance threshold off a previous year's score. Previously CMS had set the performance threshold artificially.

Changes to MIPS Performance Categories and Weights

CMS proposes to update the measures in the various performance categories for the 2022 performance year: Quality (195 measures proposed), Cost (five new episode-based measures proposed), Improvement Activities (seven new proposed and modifications to 15 existing activities) and Promoting Interoperability (revisions to the reporting requirements).

The agency also seeks comments on the process to develop cost measures which are currently developed by a CMS contractor. Since the beginning of MIPS, the agency has been challenged to develop robust cost measures that apply to all physicians.

The MIPS performance category weights are summarized below. Since these are specified in statute, they are not open for comment.

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

MIPS Participation Expanded

CMS proposes to expand the definition of MIPS eligible clinicians to include clinical social workers and certified nurse midwives.

Medicare Shared Savings Program

Key Takeaway: CMS Proposes to Extend CMS Web Interface Option for Two Years and Delay By One Year Phase-In of Increased Quality Performance Standards

In the 2021 PFS Final Rule, CMS finalized numerous policies related to ACO quality performance reporting and measurement. Specifically, for 2022, accountable care organizations (ACOs) would be 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 for MIPS survey. CMS would calculate two measures using administrative claims data. The six measures would be included in the calculation of the ACO's quality performance score for purposes of the Medicare Shared Savings Program (MSSP). In response to stakeholder pushback, CMS proposes several accommodations in this rule that ACOs may view positively.

CMS proposes to delay the requirement that ACOs report all-payer eCQM/MIPS CQM. CMS also proposes to extend the CMS Web Interface as a collection type for MSSP ACOs under the APM Performance Pathway for 2022 and 2023.

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 MIPS quality performance category score.

These proposals should be mostly welcome news to ACOs, which have raised concerns about the burden and complexity associated with the provisions in the 2021 Final Rule.

In addition, the proposed rule contains technical changes to MSSP and multiple requests for stakeholder input, including related to benchmarking and risk adjustment.

Advanced APM Track

Key Takeaway: Proposed Rule Would Codify CAA Provision to Freeze Advanced APM Thresholds at 2020 Levels

Specific revenue and patient count thresholds that APMs are required to meet to qualify for their 5% advanced APM bonus payment are set in statute. 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 proposed rule would codify this statutory change.

CMS noted that the much-anticipated Radiation Oncology Model and the Kidney Care Choices Model will be Advanced APMs in 2022, signaling that the agency may be planning to proceed with a January 1, 2022 effective date for these models.

Health Equity Initiative

Key Takeaway: CMS Solicits Comments on Data Collection Effort to Promote Health Equity

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 issued requests for information (RFIs) and proposed health equity initiatives in recent rules. In this proposed rule, CMS solicits 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 seeks feedback from stakeholders on its efforts to collect additional data to identify and respond to health disparities in its programs and policies. The agency notes several strategies it has considered, including data stratification, user-friendly results, transparency of results and provider accountability measures. CMS requests comments specifically on two areas: future stratification of quality results by race and ethnicity, and demographic data collection.

Data Stratification by Race and Ethnicity
CMS states that it does not currently collect self-reported data on race and ethnicity, which is the preferred method for acquiring accurate data that can help compare quality outcomes among different populations. Instead, CMS obtains this information from the Social Security Administration, which reduces accuracy and completeness.

The agency has attempted to improve race and ethnicity data using "indirect estimation," which uses an algorithm to predict the race and ethnicity of beneficiaries based on a combination of other data sources. The agency has also tried the method of Medicare Bayesian Improved Surname Geocoding, which attempts to use other data points and statistical analysis to estimate the likelihood of belonging to one of six ethnic groups. The agency believes the latter approach runs a relatively low risk of unintentional bias. In the long run, CMS hopes to move to self-reported race and ethnicity data.

While these methods are intended as an "intermediate step," the agency seeks comment and information on the benefits and challenges of an indirect estimation or "imputed algorithm" approach to assess hospital equity.

Improving Demographic Data Collection
One component of CMS's Quality Strategy is building better data systems through data collection standards that enhance the agency's ability to identify health disparities. This includes using common data definitions, inclusive of data on race and ethnicity for health information exchange across platforms. Long-term, the agency believes this could include social risk factors and determinants of health.

CMS seeks comment and information about the ways that hospitals currently collect demographic data, including but not limited to race, ethnicity, sex, sexual orientation and gender identity, language preference, tribal membership and disability status. The agency believes that a minimum data set that includes demographic data that is used in quality measures could help better identify disparities.

However, CMS solicits comments on challenges associated with the use of such a data set and additional improvements to the MIPS program that could address health equity.

The agency notes that it will issue additional RFIs on this topic, and that it does not intend to respond to specific comments in the final rule. It is likely that more focused RFIs will emerge in the future to inform more specific programmatic and policy responses. HHS recently updated interoperability standards with the release of the United States Core Data for Interoperability to include sexual orientation, gender identity and social determinants of health. This effort should be viewed as part of a larger effort by the Administration and across agencies to promote equity.

Removal of National Coverage Determinations

Key Takeaway: CMS Proposes to Retire Two NCDs

CMS seeks comments on its proposal to withdraw two national coverage determinations (NCDs). CMS believes that these NCDs may 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. CMS proposes to remove one NCD that provides limited coverage and one non-coverage NCD.

NCD 180.2 provides limited coverage of enteral and parenteral nutrition products. CMS proposes 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 otherwise is non-covered by NCD 220.6 unless another subsection NCD (NCDs 220.6.1 – 220.6.20) expressly covers the service. CMS proposes to remove 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 (ASP) (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 a self-administered formulation, 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 (OIG) raised concerns that this could provide perverse economic incentives. The CAA of 2021 directed the OIG 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 proposes regulations to implement this authority.

Implementation of the Appropriate Use Criteria Program

Key Takeaway: CMS Delays AUC Program Until No Earlier than January 1, 2023

The Protecting Access to Medicare Act of 2014, Section 218(b), established the Appropriate Use Criteria (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 had 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 proposed rule, CMS proposes to delay the effective date for the penalty period 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 discusses and proposes solutions for several issues and special circumstances identified by stakeholders or the agency during the testing period thus far.

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

Payment for Synthetic Skin Substitutes

Key Takeaway: CMS Proposes to Reimburse Synthetic Skin Substitutes as a Supply Cost

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 proposes the creation of eight new HCPCS codes to describe application of synthetic skin substitutes that will treat the cost of the skin substitute as a supply cost of a physician service. These codes do not distinguish between specific products, establishing a single cost for all synthetic skin substitutes.

The decision 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 practice expense reimbursed as part of a physician's service, which is not subject to use of the ASP+6% formula or product-specific price determinations. It is unclear whether a similar approach for synthetic skin substitutes as part of the 2022 rulemaking cycle is a coincidence, or whether CMS is expanding its practice of bundling drugs into physician services.

This summary does not address several topics included in the proposed rule, including but not limited to updates to vaccine administration rates, expansion of the Medicare Diabetes Prevention Program and a proposal regarding 505(b)(2) drugs.

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