UnityPoint Health

Provider Fee Schedule (PFS) Summary - FY 2022

Highlights: 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). With Biden Administration health officials within CMS appointed late into the rulemaking cycle, there were no sweeping policy proposals like last year's evaluation and management payment changes included the CY 2022 PFS proposed rule. Yet, we do see some significant policy proposals emerging from this rule addressing telehealth and other COVID-19 flexibilities; updates to the underlying practice expense data that will impact payment rates; policies across the rule promoting health equity; and enhancements and other changes to further develop physician quality initiatives.

Key Takeaways:

- 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 of 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

CMS Resources: Proposed Regulations | CMS Fact Sheet | CMS Quality Payment Program Fact Sheet
Comments Due: September 13, 2021

The below content is a topline summary of major provisions in the proposed rule.

Conversion Factor

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 conversion factor 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 20221 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.

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 does provide some 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 most 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 includes 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” practice expense inputs) are used as the first step in a multi-step calculation to generate PE RVUs. Direct PE inputs account for approximately 12 percent of PFS payments.

CY 2022 is the fourth and final year of a 4-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 the agency by submitting comments, providing invoices and meeting directly with the agency. The incorporation of these data is part of a strategy by the agency to use the most current and accurate data to value PE RVUs. Although the agency has completed this 4-year transition to new data, the agency 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 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 the Pricing of Innovative Technologies Such as Artificial Intelligence

CMS is increasingly encountering new services that have artificial/augmented intelligence (AI) or software algorithm 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 is soliciting 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

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 public health emergency (PHE), the Department of Health and Human Services (HHS) issued several waivers that made it easier to provide telehealth services to Medicare beneficiaries. These waivers – that 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 non-facility rate for office-based physicians). Use of telehealth services increased dramatically during the PHE. As we approach what is anticipated as the end of PHE; providers, patients, and other stakeholders are urging Congress and CMS to allow continued access to

telehealth services by maintaining these flexibilities. This focused attention on telehealth has made the agency's telehealth proposals highly anticipated.

In this proposed rule, CMS proposes temporary extension of telehealth coverage for certain services through CY 2023. This temporary extension will allow the agency to collect more data to inform the structure of the telehealth coverage in a post-COVID-19 environment. As demand for telehealth beyond the pandemic has grown, critical issues for the agency have been determining which services can be appropriately provided via telehealth from a clinical perspective; and addressing fraud and abuse. The agency has also indicated that the experience of COVID-19 has shown them that such policies may also help address disparities.

Key telehealth proposals are outlined below

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, they have declined to propose any codes. CMS discusses in the rule that they do not feel 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	Proposals to Expand Access to Treatment of Mental Health Disorders 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 (RHCs) and Federally Qualified Health Centers (FQHCs) provided 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. These practitioners will be required to have the capacity to furnish*

	two- way, audio/video telehealth services but are 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 In the CY 2021 PFS Proposed 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. *CMS is proposing to permanently adopt coding and payment for code G2252*

While the proposal does temporarily extend coverage for certain services, once the PHE ends Congressional action is needed 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 have generated a significant level of interest from a variety of stakeholders prior to the pandemic. During the PHE, CMS implemented a number of flexibilities to allow for broader use of these services although there was limited guidance from CMS on the reporting of these services. Industry expectation was that there would be a significant increase in the use of these codes in CY 2020 and that, in response, CMS might propose additional policies to further clarify and potentially limit the use of these codes.

While there was a more than five-fold increase in utilization for some of the RPM codes, 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. In addition, the agency is seeking feedback from stakeholders on the types of devices that may be applicable for the RTM codes.

A number of questions remain surrounding these RPM codes:

- How is CMS going to operationalize the specific requirements for these codes?
- Will CMS require specific details 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?

The lack of additional restrictions will be welcomed by providers and medical device manufacturers and suppliers 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 Implements a Statutory Change to Reduce Patient Financial Burden for Screening Colonoscopies

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 it was removed, then the procedure was not to be billed as a screening but a diagnostic procedure, subject to standard co-insurance requirements.

Following a statutory change in the Consolidated Appropriations Act of 2021, CMS is making two regulatory changes that will reduce the financial burden of colorectal cancer screening to beneficiaries. The first change is that screening colonoscopies and sigmoidoscopies that detect a lesion and lead to tissue removal, will be treated as screening rather diagnostic procedures and subject to special screening payment provisions. Additionally, CMS will 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 will be welcomed by providers and patients alike who have both 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 Amends Regulations to Allow PAs to Directly Bill Medicare

Nonphysician practitioners (NPPs), including Nurse Practitioners, Clinical Nurse Specialists, and Physician Assistants are able to provide physician services (as defined by the Social Security Act) under Medicare and receive a reimbursement rate of 85% of the PFS payment rate. However, unlike the other two types of NPPs, statutory restrictions have prohibited PAs from being able to bill Medicare for services; a physician employer was required to bill. The 2021 Consolidated Appropriations Act will permit PAs to directly bill Medicare effective 2022, so CMS is proposing regulatory changes to conform to the statutory change.

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

Potentially Misvalued Codes

Key Takeaway: CMS Solicits Comments on 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. 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 (eg, laminaria, prostaglandin) (separate procedure)
66982	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, 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 concerns stakeholders when one of their services is proposed for revaluation under the Potentially Misvalued Code process.

Quality Payment Program

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 sunset traditional MIPS. The proposals described below are open for comment.

- MVP Criteria: The agency has proposed updates to the MVP criteria including a requirement of at least one outcome measure, inclusion of one high priority measure relevant to each specialty participating in the MVP and that any Qualified Clinical Data Registry measures must be fully tested.
- MVP Implementation Timeline: CMS proposes to initiate the MVP program in CY 2023. The agency says they are providing 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 is proposing 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 in CY 2027.

Over the years, Traditional MIPS has been criticized by some as being expensive and time consuming with very little positive payment adjustments as a reward and a lack of clarity on its impact on patient care. Yet, with MVPs being untested and uncertainty if there will be MVP options for all participants, some stakeholders may raise concerns about the proposal to sunset Traditional MIPS. While still years away, stakeholders may urge CMS to provide further details on the transition process.

Key Takeaway: CMS Increases 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 the performance threshold had been artificially set by CMS.

Changes to MIPS Performance Categories and Weights

CMS is proposing 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 measures) and Promoting Interoperability (revisions to the reporting requirements).

Cost measures are developed by a CMS contractor. The agency is also seeking comments on the process to develop cost measures. 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%

CMS is proposing to expand the definition of a MIPS eligible clinician to include clinical social workers and certified nurse mid-wives

Medicare Shared Savings Program (MSSP)

Key Takeaway: CMS Proposes a Longer Transition to ACO eCQM/MIPS CQM Quality Measure Reporting by Extending the CMS Web Interface Option for Two Years. CMS is also Proposing an Additional Year before the Phase in of the Increased Quality Performance Standard ACOs Must Meet to Share in Savings

In the 2021 PFS Final Rule, CMS finalized numerous policies related to ACO quality performance reporting and measurement. Specifically, for 2022, ACOs would have been required to actively report quality data on three eCQM/MIPS CQM measures (electronic clinical quality measures/MIPS clinical quality measures) and field the CAHPS (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

ACOs quality performance score for purposes of the MSSP. In response to stakeholder pushback, CMS is making several accommodations in this rule that may be viewed positively by ACOs. CMS is proposing to delay the requirement that ACOs report all-payer eCQM/MIPS CQM measures. CMS is also proposing to extend the CMS Web Interface as a collection type for MSSP ACOs under the APM Performance Pathway for 2022 and 2023.

CMS is also proposing 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 measures in PY 2022 and 2023. In PY 2024, the threshold for quality performance standard will increase to the 40th percentile MIPS quality performance category score.

These proposals should be mostly welcome news to ACOs who have raised concerns about the burden and complexity associated with the provisions in the 2021 Final Rule.
In addition, the proposed rule contains some additional technical changes to MSSP and multiple requests for stakeholder input, including related to benchmarking and risk adjustment.

Advance APM Track

Key Takeaway: Proposed Rule Codifies 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 codifies this statutory change.

CMS also noted that the much-anticipated Radiation Oncology Model, as well as the Kidney Care Choices Model, will be an Advanced APM 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 is soliciting comments on how to improve the collection and utility of data around health disparities that arise from social risk factors, including race and ethnicity.

Removal of National Coverage Determinations (NCDs)

Key Takeaway: CMS Proposes to Retire Two NCDs

CMS seeks comments on its proposal to withdraw two 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 discretion of the MAC. CMS believes this will result in greater contractor flexibility and will better serve the needs of Medicare beneficiaries. CMS is removing one NCD that provides limited coverage and one non-coverage NCD.

NCD 180.2 provides limited coverage of enteral and parenteral nutrition products. CMS is proposing 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 FDA 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 is proposing 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 (ASP) 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 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 a HCPCS code to which a price is assigned. When one or more of the formulations of a drug crosswalked to a HCPCS code is 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 getting paid substantially more than 106% of the drug's cost. The Office of the 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 is proposing regulations to implement this authority.

Implementation of the Appropriate Use Criteria (AUC) 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 the January after the end of the COVID-19 PHE. During the penalty period, any claims that do not meet the requirements for the program will be denied or rejected. In addition to the delayed penalty phase, CMS discusses and proposes solutions for a number of issues and special circumstances identified by the stakeholders and/or by 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 is seeking 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 OPPS to reimburse application of synthetic skin substitutes in the outpatient hospital setting, but this 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 rule making 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 is proposing 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. Furthermore, 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 in so doing 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 rule making cycle is a coincidence, or CMS is expanding its use 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.*

For more detailed information on specific provisions, please reach out to:

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