

# Special Bulletin

July 14, 2021

# CMS Releases CY 2022 Proposed Rule for Physician Fee Schedule Payments

The Centers for Medicare & Medicaid Services (CMS) July 13 issued a proposed rule that would update physician fee schedule (PFS) payments for calendar year (CY) 2022. The rule also includes several proposals to implement changes to the quality payment program (QPP) created by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015.

AHA Take: The AHA is closely evaluating CMS' proposals. We appreciate the proposed enforcement delay of the Appropriate Use Criteria (AUC) program, as well as the proposal to expand access to telehealth for behavioral health services.

However, we continue to have concerns regarding certain aspects of the pricing methodology for drugs administered as part of the Opioid Treatment Program benefit, including the limitations on takehome supplies of naloxone. Moreover, we remain concerned about the feasibility of the Merit-Based Incentive Payment System (MIPS) Value Pathways, and believe much work remains to ensure they result in fair, equitable performance comparisons across MIPS clinicians and groups.

CMS will accept comments on this rule through 5 p.m. on Sept. 13. Highlights of the PFS proposed rule follow. Watch for a detailed Regulatory Advisory in the coming weeks.

#### **Key Takeaways**

CMS proposes to:

- Reduce the PFS conversion factor by 0.14% for CY 2022, as well as eliminate the CY 2021 one-year 3.75% conversion factor increase.
- Delay implementation of the penalty phase of the AUC program to the later of Jan. 1, 2023, or the Jan. 1 that follows the end of the COVID-19 public health emergency.
- Allow providers to receive payment for mental health services provided via telehealth if they conduct initial and periodic in-person visits and allow audioonly behavioral health services in certain circumstances.
- Allow rural health clinics and federally qualified health centers to report and receive payment for mental health visits furnished via telehealth, including via audio-only connection in certain circumstances.
- Extend the compliance date for eprescribing of controlled substances to 2023.
- Implement seven optional MIPS Value pathways beginning in 2023.
- Increase the MIPS performance threshold.
- Phase-in the requirement to report the MIPS APM Performance Pathway (APP) measure set over the course of 2022 and 2023.

#### CY 2022 PROPOSED PAYMENT UPDATE

The proposed payment update for CY 2022 reflects several different factors, some of which are unique to this year to account for policy changes implemented last year. The Consolidated Appropriations Act of 2021 (CAA) provided a 3.75% increase in the PFS conversion factor for CY 2021 *only*. This one-year increase was meant to offset the significant, 10.20% physician fee schedule (PFS) conversion factor decrease that CMS finalized for that year. Because the CAA instructed CMS to ignore the 3.75% increase when determining PFS payment rates for subsequent years, the agency calculated the CY 2022 conversion factor as though the 3.75% increase never occurred. Thus, CMS proposes a slight decrease in PFS payment rates of 0.14% in CY 2022. **However, the actual change from the final CY 2021 conversion factor of \$34.89 to the proposed CY 2022 conversion factor of \$33.58 is a decrease of \$1.31 or 3.89%**. This reflects the expiration of the 3.75% payment increase, a 0% update factor as required by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, and a budget-neutrality adjustment.

#### **APPROPRIATE USE CRITERIA**

Appropriate Use Criteria (AUC) are a set of individual criteria that present information linking a specific clinical condition or presentation with one or more services and an assessment of the appropriateness of the services. The Protecting Access to Medicare Act (PAMA) of 2014 required CMS to establish a program to promote the use of AUC for advanced diagnostic imaging that integrates AUC into the clinical workflow.

In this rule, CMS provides clarifications and proposals related to the scope of the AUC program and in response to claims processing issues that have arisen, among other proposals. In addition, in light of the complexities of these changes and the AUC program itself, as well as the ongoing COVID-19 public health emergency (PHE), CMS proposes to delay the payment penalty phase of the program to the later of Jan. 1, 2023, or the Jan. 1 that follows the end of the PHE. The agency seeks comment on the proposed start date for the payment penalty phase of the program and whether it sufficiently accounts for the COVID-19 pandemic.

#### Changes to Payment for Medicare Telehealth Services

This rule includes several proposals to extend temporary coverage of some telehealth services and make permanent coverage and payment for other services.

In the CY 2021 PFS final rule, CMS created a new category – Category 3 – for adding services to the approved list of Medicare telehealth services on a temporary basis. Also in the CY 2021 rule, CMS added several services to the Medicare list of telehealth services on a Category 3 basis, establishing coverage and payment for those services through the end of the year in which the PHE expires. In this rule, the agency proposes to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023.

CMS also proposes to implement certain telehealth-related provisions of the CAA that addressed the provision of mental health telehealth services, which are services for the diagnosis, evaluation or treatment of mental health disorders. Specifically, as directed by the statute, CMS proposes to require providers to conduct an in-person, non-telehealth service within six months prior to providing an initial telehealth mental health service, and at least once every six months thereafter. This requirement would apply only to the mental health telehealth services made possible by the CAA; that is, it would apply only to services delivered to patients in their homes (regardless of the geographic location of the patient) and services delivered to patients in geographic locations beyond those currently authorized for Medicare telehealth services.

Regarding audio-only telehealth services, CMS proposes to allow the use of audio-only communication for the diagnosis, evaluation, or treatment of mental health disorders furnished to established patients in their homes, but only if the beneficiary is unable to use, does not wish to use, or does not have access to two-way, audio/video technology. CMS requests comments on whether it should establish any additional guardrails for the provision of audio-only telehealth services for mental health care.

### PAYMENT FOR EVALUATION AND MANAGEMENT (E/M) VISITS

Over the course of several years of PFS rules, CMS has engaged in an ongoing review of payment for E/M visit code sets. In this rule, CMS makes various more narrow proposals that refine some aspects of the E/M visit code set, including: (1) "split" or shared E/M visits performed in a facility setting by a physician and non-physician practitioner (NPP) in the same group; (2) critical care services; and (3) teaching physician services.

# BILLING AND PAYMENT FOR RURAL HEALTH CLINICS (RHCs) AND FEDERALLY QUALIFIED HEALTH CENTERS (FQHCs)

CMS makes several proposals designed to bolster the ability of RHCs and FQHCs to serve their patients. Of note, CMS proposes to allow RHCs and FQHCs to deliver mental health services via telehealth after the COVID-19 PHE flexibilities expire. Under this proposal, RHCs and FQHCs – which are not authorized to serve as distant site practitioners for Medicare telehealth services – would be allowed to report and receive payment for mental health visits furnished via real-time telecommunication technology in the same way they currently do for in-person visits. This would include audio-only visits when the beneficiary is not capable of, or does not consent to, the use of video technology. The rule also includes additional proposals regarding billing by and payment to RHCs and FQHCs and a comment solicitation on tribal FQHC payments.

#### REQUEST FOR COMMENTS REGARDING VACCINE ADMINISTRATION SERVICES

CMS is soliciting comments on the costs involved in furnishing preventive vaccines, like pneumonia, flu and hepatitis B. In the proposed rule, the agency acknowledges an

almost 30% decrease in Medicare payment rates over the last several years for the administration of certain preventive vaccines. CMS intends to use the information it receives to assist in developing more accurate rates for the provisions of these services. Specifically, the agency seeks information on the following:

- The different types of health care providers who administer vaccines and how that has changed since the beginning of the pandemic;
- How the costs of furnishing flu, pneumococcal and hepatitis B vaccines compare to the cost of furnishing COVID-19 vaccines; and
- How the PHE may have impacted costs, including whether those costs will continue beyond the PHE.

Additionally, CMS seeks input on the current \$35 add-on payment for certain vulnerable beneficiaries who receive the COVID-19 vaccine at home, as well as what should qualify as "home" to ensure beneficiary access without sacrificing program integrity. Finally, in its proposal, the agency asks for input on whether COVID-19 monoclonal antibody treatments should be treated in the same way other physician-administered drugs and biological products are under Part B.

#### MEDICARE PROVIDER ENROLLMENT

CMS proposes several revisions to the provider enrollment regulations, including: expanding the agency's authority to deny or revoke a provider's or supplier's Medicare enrollment; establishing certain rebuttal procedures for providers and suppliers whose Medicare billing privileges have been deactivated; and exempting certain types of independent diagnostic testing facilities (IDTF) from several IDTF supplier standards.

### **OPIOID TREATMENT PROGRAM (OTP) PROVISIONS**

CMS proposes several modification to regulations regarding the Part B OTP benefit established in previous rulemaking. First, CMS proposes to adjust payments for takehome supplies of naloxone (including both the drug and associated services, finalized in the CY 2021 PFS final rule) for geographic and Medicare spending variation. In addition, CMS would create a new G-code describing a take-home supply of a new, higher dose naloxone product, and price the code using the same methodology used for existing codes in the benefit.

Finally, CMS proposes to allow OTPs to continue to furnish therapy and counseling using audio-only telephone calls rather than via two-way interactive audio/video communication technology following the end of the PHE for COVID-19. CMS stipulates in its proposal that this would only be permitted where audio/video communication is not available to the beneficiary — meaning, the beneficiary is not capable of or has not consented to the use of the technology — and all other applicable requirements are met. In addition, OTPs would be required to append a specific modifier to claims and document in the beneficiary's medical record that the counseling or therapy was

furnished via audio-only and the rationale for doing so. These requirements would take effect Jan. 1, 2022, but would apply only for services furnished after the end of the PHE.

# ELECTRONIC PRESCRIBING OF CONTROLLED SUBSTANCES (ECPS) FOR PART D DRUGS

The CY 2021 PFS final rule implemented Section 2003 of the SUPPORT Act mandating electronic prescribing of Schedule II-V controlled substances under Medicare Part D beginning Jan. 1, 2021. The rule established Jan. 1, 2022 as a compliance date for this requirement. However, based on stakeholder feedback and consideration of challenges brought on by the COVID-19 pandemic, CMS is proposing to extend the compliance date for ECPS requirements until Jan. 1, 2023. CMS would further extend the compliance date for Part D controlled substance prescriptions written for beneficiaries in long-term care facilities until Jan. 1, 2025 due to the unique circumstances of these providers.

In addition to revisions to the timing of these requirements, CMS also proposes that in order for prescribers to be considered compliant, they must prescribe at least 70% of their Part D controlled substance prescriptions electronically per calendar year. Proposed exceptions to this requirement would be for prescriptions issued where the prescriber and dispensing pharmacy are the same entity, prescribers who prescribe 100 or fewer Part D controlled substance prescriptions per year, prescribers who are prescribing during a recognized emergency (like a natural disaster or pandemic), and prescribers who request and receive a waiver from CMS due to extraordinary circumstances.

CMS proposes that its compliance actions in CY 2023 would consist of sending letters to prescribers that the agency believes are violating the EPCS requirement during that period of time. The agency states that it will consider whether further compliance actions will be necessary in future rulemaking.

### QUALITY PAYMENT PROGRAM (QPP)

As mandated by MACRA, the QPP includes two tracks – the default Merit-Based Incentive Payment System (MIPS) and advanced alternative payment models (APMs). The rule proposes updates to what eligible clinicians must report during the QPP's 2022 performance period and beyond. There is a lag of two years between the QPP's performance period and the payment year; for example, CY 2022 performance will affect PFS payments in CY 2024.

As required by MACRA, eligible clinicians will receive positive or negative payment adjustments of up to 9% in CY 2024 based on CY 2022 performance. This is the maximum adjustment allowed under MACRA. Key proposed MIPS policy changes include the following:

- MIPS Value Pathways (MVPs). In prior rulemaking, CMS adopted a framework for MVPs that the agency intends as a replacement for the current MIPS. MVPs organize the reporting requirements for each MIPS category around specific medical conditions, clinical specialties or episodes of care. In this rule, CMS proposes seven optional MVPs beginning with the CY 2023 performance period. The MVPs include rheumatology, stroke care and prevention, heart disease, chronic disease management, lower extremity joint repair (e.g., knee replacement), emergency medicine and anesthesia. CMS also invites comment on when it should mandate MVP participation for all MIPS participants, suggesting that it aims to sunset the current MIPS approach after the CY 2027 performance period.
- MIPS Performance Threshold. The performance threshold is the total MIPS score at which neutral MIPS payment adjustments apply; scores above or below the threshold result in positive or negative adjustments respectively. CMS proposes to increase the performance threshold for the CY 2022 performance/CY 2024 payment year from 60 to 75 points. As required by law, this threshold is the mean MIPS performance score from a prior payment adjustment year (in this case, CY 2019).
- Promoting Interoperability. CMS proposes to make changes to the category's objectives and measures for CY 2022 that align with changes proposed for the hospital Promoting Interoperability Program. These include revising requirements for the Public Health and Clinical Data Exchange objective, requiring eligible clinicians to attest to an annual assessment of the High-Priority Guide of the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) and modifying the Prevention of Information Blocking attestation statements.
- Health Equity Request for Information (RFI). The proposed rule includes an RFI asking for feedback on several ways CMS is considering using the QPP to advance health equity. For example, the agency is considering clinician and/or public-facing reports on MIPS quality measures stratified by dual-eligible status, race and other factors. CMS also asks for comment on ways of increasing the collection of demographic and social risk data, including the collection of a "minimum set" of demographic elements (e.g., race, ethnicity, language, disability status) that could be used for a variety of tracking and quality measurement purposes. The agency is considering using EHRs as a data collection mechanism.

## MEDICARE SHARED SAVINGS PROGRAM (MSSP)

CMS proposes several changes to the MSSP program, including to the quality measure set participants must report.

**Quality Measurement.** In last year's PFS final rule, CMS adopted a policy in which it reduced the MSSP quality measure set to the same six measures used in the MIPS APM Performance Pathway (APP), and increased the minimum quality score accountable care organizations (ACOs) would have to achieve to qualify for shared savings or avoid owning maximum losses. In response to concerns about the proposal,

CMS proposes a longer phase-in of the requirement to report the APP performance measure set. Specifically, ACOs would be permitted to report either the current MSSP measure set via the web interface, or the MIPS APP measure set in performance years 2022 and 2023. In CY 2023, those ACOs that choose to report the web interface measure set also would be required to report at least one measure from the APP measure set. In addition, CMS proposes to delay the increase of the minimum quality standard from the 30<sup>th</sup> to the 40<sup>th</sup> percentile until the CY 2024 performance year.

Changes to Other Programmatic Elements of the MSSP. CMS proposes several other changes to various elements of the MSSP, including the requirements around establishing repayment mechanisms, the MSSP application process, beneficiary notification requirements, and the definition of primary care services that is used for beneficiary assignment. CMS also seeks comment on considerations related to the use of regional fee-for-service expenditures in establishing, adjusting, updating and resetting the ACOs' historical benchmarks.

#### **NEXT STEPS**

Watch for a more detailed Regulatory Advisory in the coming weeks. Comments on the proposed rule are due to CMS on or before Sept. 13. If you have further questions on the payment provisions, please contact Shira Hollander, senior associate director of policy, at <a href="mailto:shollander@aha.org">shollander@aha.org</a>; for questions on quality provisions, please contact Akin Demehin, director of policy, at <a href="mailto:ademehin@aha.org">ademehin@aha.org</a>.