compliance

Highlights of the CY 2024 MPFS and HOPPS Proposed Rules

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n July 13, 2023, the Centers for Medicare & Medicaid Services (CMS) released its proposed rules for calendar year (CY) 2023 the Medicare Physician Fee Schedule¹ (MPFS) and Hospital Outpatient Prospective Payment System² (HOPPS). Once again, a main highlight of the proposed MPFS is a reduction in the conversion factor, resulting in payment reductions. For HOPPS, the main new issue is a proposed increase in payments for CY 2024, which may be offset by the 340B Drug Discount Program payback adjustment.³

MEDICARE PHYSICIAN FEE SCHEDULE

Payment Rates

The MPFS provides the regulatory information and payment rates for physicians—no matter what setting they work in (facility and nonfacility) or who employs them—and office-based (non-facility) settings. Stakeholders had until 5:00 PM on September 11 (60 days) to submit comments to CMS on the proposed changes for CY 2024.

A value established each calendar year by building on the conversion factor (CF) from the preceding year, the CF converts the relative value units (RVUs) of physician work, the practice expense (PE) and malpractice expense of each code, and their geographic locations into the assigned CMS payment rate. As defined in previous legislation, the CF has a statutory increase of 0 percent through CY 2025; any adjustments are solely due to other regulatory actions or maintenance of the Medicare budget constraints.

For CY 2024, CMS was required, per the Consolidated Appropriations Act of 2023⁴, to

reduce the CY 2023 CF (\$33.8872) by 2.5 percent first before determining the base value to begin the 2024 calculations. The decrease was a result of the one-time only increase legislated for the CY 2023 CF; the CF base for 2024 was \$33.0607. CMS is proposing a decrease of 2.17 percent for budget neutrality, due to proposed 2024 total payments over the budget limitations, but this decrease is "softened" by the 1.25 percent increase required by the same act. Considering these factors, CMS proposes a CF of \$32.7476, an estimated 3.34 percent decrease from 2023. Below is the impact on facility and non-facility settings as estimated per the total allowed charges for CY 2024.

- Hematology/Oncology Combined Impact: Total: 2%, Non-facility: 1%, and Facility: 2%
- Radiation Oncology and Radiation Therapy Centers Combined Impact: Total: -2%, Non-facility: -2%, and Facility: -2%

The reduction of the CF does result in decreases for many specialties and their estimated impacts; however, additional decreases are proposed to RVUs due to misvalued codes, the inclusion of the office/outpatient evaluation and management (E/M) complexity add-on code, year 3 phase-in of clinical labor updates, and proposed adjustments to behavioral health services.

Specific Codes and Code Set Valuations

Within the CY 2024 proposed rule, CMS addressed multiple misvalued and/or proposed value changes to specific series of new and established CPT® codes. The agency explains the rationale for the proposed changes are based on values recommended by AMA

Specialty Society Relative Value Scale Update Committee (RUC) and other organizations which CMS uses for assistance in setting appropriate values for codes.

Changes to Advanced Care Planning CPT Codes 99497 and 99498

The RUC's Relativity Assessment Workgroup (RAW) reviewed codes **99497** and **99498** in January 2022, and determined these codes should be examined due to the changes in the E/M services. At its April 2022 meeting, the RUC recommended no changes in physician time, work RVUs, or direct PE inputs for these services. For 2024, CMS is proposing the RUC-recommended work RVU of 1.50 for code **99497** and 1.40 for code **99498**, which are the current values for these codes; and the RUC-recommended direct PE inputs without refinement.

Hyperthermic Intraperitoneal Chemotherapy (HIPEC) CPT Codes

In September 2022, 2 time-based add-on Category I CPT codes were created:

- 9X034 (Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; first 60 minutes)
- 9X035 (Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; each additional 30 minutes).

During the January 2023 RUC meeting, specialty societies noted that the data reflected time estimates that were higher than the time

specified in these time-based codes. The RUC concluded the survey results for these codes were incorrect, and therefore should be resurveyed for 2025. Based on this, the RUC recommended contractor pricing and referral to the CPT Editorial Panel for revision. For CY 2024, CMS is proposing the RUC-recommended contractor pricing for codes **9X034** and **9X035**.

E/M Visits

In the MPFS proposed rule for CY 2024, CMS is addressing 2 outstanding E/M visit payment issues: implementing separate payment for the E/M visit complexity add-on payment and the definition of split (or shared visits) which was delayed for CY 2023.

E/M Visit Complexity Add-On

Prior to the E/M changes that began in 2021, CMS was not in agreement with AMA, so the agency created an add-on code to recognize complex care provided to Medicare beneficiaries not represented in the updated values. The add-on code, **G2211**: (Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. [add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established]), was proposed as part of the CY 2021 proposed rule.

After code **G2211** was established, the Consolidated Appropriations Act of 20215 put a moratorium on Medicare payment for this service by disallowing CMS from reimbursing it under the MPFS before January 1, 2024. For CY 2023, the rest of the E/M visit code families (except critical care services) were revised to match the general framework of the E/M visits, including visit level selection based on time or medical decision-making (MDM) level. Despite revisions to the Other E/M visit families in the CY 2023 final rule, CMS believed certain types of E/M visits still did not account for the complexity and resources needed to perform certain types of care.

CMS is proposing to change the code status

indicator of **G2211** from "B" (bundled) to "A" (active), effective January 1, 2024. Based on feedback received, CMS is also proposing policy revisions relating to HCPCS code **G2211**, including it would not be payable when the E/M visit code is reported with payment **modifier 25** due to performance with a minor procedure. The components of the minor procedure, along with the E/M, would negate the opportunity to bill for the added complexity.

Split (or Shared) Visits

For CY 2024, CMS is proposing to again delay the implementation of its definition of "substantiative portion" as more than half of the total provider time through at least December 31, 2024. In addition, CMS is proposing to maintain the current definition of the substantiative portion that allows for use of either 1 of the 3 key components (history, exam, or MDM); or more than half the total time spent to determine the billing practitioner. The delay will also allow stakeholders more time to consider the proposals and provide feedback for future rulemaking.

Telephone E/M Services

In previous rulemaking and in response to the COVID-19 public health emergency (PHE), CMS recognized and finalized separate payment for E/M services furnished via telephone, CPT codes **99441–99443** and **98966–98968**. Codes 99441-99443 are telehealth services and will continue coverage and payment by CMS through December 31, 2024. Codes 98966-**98968**, which describe telephone assessment and management by non-physician healthcare professionals, are not considered telehealth services by CMS. For CY 2024, CMS is proposing to continue payment for CPT codes 98966-**98968**, extending the telehealth-related flexibilities provided to other audio-only services covered in the Consolidated Appropriations Act of 2023.1

Complex Drug Administration Payments

CMS has received several comments concerning payments for nonchemotherapeutic complex drug administrations. Specifically, these

payments are not in alignment with or inadequate considering the resources and costs to provide the infusion services. Stakeholders have stated these infusion services are like complex chemotherapy and other highly complex biological agent administration ("chemotherapy administration") services billed with CPT codes **96401–96549**, rather than the therapeutic, prophylactic, and diagnostic injections and infusion services CPT codes **96360–96379**.

For CY 2024, CMS is seeking comments regarding Part B drug payment policies to promote consistency in payment and patient access. CMS is gathering resources relevant to help the agency determine the appropriate coding and payments for complex nonchemotherapeutic drug administrations. CMS is also seeking comments on whether the agency should revise policy guidelines to better reflect how specific infusion services are furnished and should be billed.

Physician Supervision Via Two-way Audio/Video

For CY 2024, CMS is proposing to extend the definition that allowance for direct supervision to be met with the use of real-time audio and video interactive telecommunications through December 31, 2024. This extension would align with the timeframe of many PHE-related telehealth policies and avoid an abrupt transition to pre-PHE policies. CMS is also seeking comments on whether the definition of direct supervision to permit virtual presence should be extended beyond December 31, 2024.

Residents in Teaching Settings

For CY 2024, CMS is proposing to allow the teaching physician to have a virtual presence in all teaching settings, but only in clinical instances when the service is furnished virtually (3-way telehealth visit, with all parties in separate locations). The proposal would permit teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service through real-time audio/video communication for all residency training locations through December 31, 2024.

New Codes for CHI, SDOH, and PIN Services

A primary focus for CMS now is related to equity in and access to care and how social determinants of health (SDOH) impact the ability to diagnose or treat the patient. As part of this focus, CMS is trying to determine how to improve payment accuracy for additional time and resources dedicated to helping patients with serious illnesses as they navigate the healthcare system or remove health-related social barriers.

CMS is proposing to create two new G codes describing Community Health Integration (CHI) services performed by certified or trained auxiliary personnel, such as a community health worker (CHW), incident to the physician services, but under general supervision. The proposal would include CHI services furnished monthly, as medically necessary, once a CHI initiating E/M visit is provided. The practitioner would need to identify the social determinants of health (SDOHs) that significantly limit their ability to diagnose or treat the problem(s) addressed in the visit.

For CY 2024, CMS is proposing a single G code to identify and value the work involved in administering a SDOH risk assessment as part of a comprehensive social history in relation to an E/M visit; this code would be furnished on the same date as the E/M. CMS is also proposing 2 principal illness navigation (PIN) services codes that would be provided under general supervision, following an initiating E/M visit addressing a serious high-risk condition/illness/disease.

HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

Payment Rates

The Outpatient Department (OPD) increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital charges. CMS proposed a 2.8 percent increase to the OPD fee schedule.

The agency estimates total payments to HOPPS providers will be approximately \$88.6 billion, an increase of approximately \$6.0 billion compared to CY 2023 HOPPS payments.

In July of 2023, CMS published a proposed rule referred to as the "remedy proposed rule", to address the reduced 340B Drug Discount Program payment amounts for CYs 2018 through 2022 while complying with budget neutrality. The remedy proposed rule does not offer any changes to CMS' proposed CY 2024 HOPPS drug payment policy or conversion factor but does propose changes to the calculations of the HOPPS conversion factor beginning in CY 2025. For CY 2024 CMS proposes to continue to pay the default rate, which is generally ASP+6 percent, for 340B acquired drugs and biologicals.

Cancer Hospital Payment Adjustment

CMS proposed to continue for CY 2024 the additional payments to cancer hospitals using a payment-to-cost ratio (PCR) factor. Beginning in CY 2018, the 21st Century Cures Act required the weighted average PCR be reduced by 1.0 percentage point. CMS proposed a target PCR of 0.88 to determine the CY 2024 cancer hospital payment adjustment to be paid at cost report settlement, which includes the 1.0 percent reduction; this is a decrease from recent year adjustment factors.

Payments of Drugs, Biologicals (Including Biosimilar Products), and Radiopharmaceuticals

Each year CMS assesses payments for drugs and biologicals based on current pricing methodologies, which includes payments for drugs and biologicals considered separately payable based on the assigned APC or pass-through status. For CY 2024, CMS proposed to continue the current payment policy in effect since CY 2013. Additionally, CMS indicated it does not believe the agency must continue to propose the longstanding payment policies year-after-year. Instead, only if there is a change to a policy regarding payment for drugs, biologicals (including biosimilars), and radiopharmaceuticals will the proposed policy be outlined.

The few items in which CMS is proposing new policy or payment incudes:

- CMS proposed to package drugs and biologicals estimated at a per day administration cost less than or equal to \$140; in CY 2023 this amount was set at less than or equal to \$135.
- Proposal to except biosimilars from the threshold packaging policy when their reference biologicals are separately paid.
 If a reference product's per-day cost falls below the threshold packaging policy, CMS has proposed that all the biosimilars related to the reference product would be similarly packaged regardless of whether their per-day costs are above the threshold.
- Proposal to simplify the process of reporting drugs purchased under the 340B Drug Discount Program by using only the "TB" modifier to identify drugs. Hospitals would report the "TB" modifier effective January 1, 2025, even if the hospital previously reported the "JG" modifier. In addition, the "TB" modifier descriptor: (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities) would be changed effective January 1, 2024, to no longer include "...for select entities" as all entities would report this modifier after this date.

Proposal to Remedy Payment Adjustment for 340B-Acquired Drugs from CY 2018 Through September 27 of CY 2022

Due to a Supreme Court ruling on the 340B Drug Discount Program, on July 7, 2023, CMS uploaded a revised payment file for HOPPS drugs to be paid at ASP+6 percent from September 28, 2022, through December 31, 2022. For CY 2023, CMS reduced the HOPPS conversion factor by 3.09 percent for budget neutrality, due to the adjustment from ASP-22.5 percent to ASP+6 percent for qualifying drug payments. The agency still needed to address and propose a plan for paying back monies from January 1, 2018, through September 27, 2022. CMS addresses this in a separate proposal from the CY 2023 HOPPS proposal; Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-

Acquired Drug Payment Policy for Calendar Years 2018-2022, CMS-1793-P.³ In its proposal, CMS considered the following ways to remedy the needed payment adjustments.

- Make additional payments to affected 340B covered entity hospitals for 340B-acquired drugs from CY 2018 through September 27 of CY 2022 without proposing an adjustment to maintain budget neutrality.
- 2. Full claims reprocessing from January 1, 2018, through September 27, 2022.
- 3. Aggregate hospital payments from January 1, 2018, through September 27, 2022.

CMS believes the best way to remedy the payment adjustments is to make a one-time lump sum payment to affected 340B covered entities, by calculating the difference between what they were paid for 340B drugs (ASP-22.5 percent or an adjusted wholesale acquisition cost [WAC] or average wholesale price [AWP] amount) between January 1, 2018, through September 27, 2022, and that amount that would have been paid if ASP+6 percent were applied. CMS believes this method will be easier than reprocessing clams and the burden that would create.

Approximately 1,649 340B covered entity hospitals were paid at the 340B payment rate (ASP-22.5 percent) January 1, 2018, through September 27, 2022. CMS estimates these hospitals were paid approximately \$10.5 billion less than if the reduction had not been in place. These figures are expected to be updated in the final HOPPS rule as the agency continues to receive updated claims data for CY 2022, which would be claims submitted by September 27, 2023.

CMS estimates 340B providers have already received \$1.5 billion in remedy payments from reprocessed claims from January 1, 2022, through September 27, 2022, reducing the overall estimated payment amount to \$9.0 billion. CMS then calculated the estimated aggregate payments for 340B drugs assigned status indicator (SI) "K" (non-pass-through drugs and non-implantable biologicals, including therapeutic radiopharmaceuticals) and billed with modifier "JG" (drug or biological acquired with 340B Program

discount, reported for informational purposes), and their difference between the payment policy rates (ASP+6 percent vs. ASP-22.5 percent, or the corresponding WAC or AWP). CMS invited comments on its methodology.

To determine the amount owed to each hospital, CMS proposes to calculate how much each hospital would have been paid if the policy was ASP+6 percent, January 1, 2018, through September 27, 2022, for drugs acquired through 340B Program, minus any remedy payments already made to each respective hospital. For example, if a hospital was estimated to have been paid \$10 million for 340B drugs, and with the reduced payment policy the hospital was paid \$7.31 million for the 340B drugs, the difference is \$2.69 million and that difference would be the lump sum payback amount.

CMS will provide instructions to the Medicare Administrative Contractors (MACs) to remit payments to the hospitals within their jurisdiction. Each MAC would have 60 calendar days to make these payments. CMS specifically asked for comments on the payback timeline.

To address beneficiary cost-sharing, CMS estimates \$1.8 billion is the amount paid by beneficiaries as part of their cost sharing (co-payment) to the covered hospitals; estimated from the \$9 billion total owed to 340B covered hospitals. CMS proposes 340B covered entities may not bill beneficiaries for coinsurance on remedy payments, regardless of any adjustment.

Non-drug services under HOPPS were increased from January 1, 2018, through December 31, 2022. CMS must calculate these increases to offset the remedy payments made and maintain budget neutrality. A reduction of 3.09 percent was already applied for CY 2023. To determine the amount paid for the non-drug services, CMS includes codes reported during the time in question and assigned SI (status indicators) of J1, J2, P, Q1, Q2, Q3, R, S, T, U, and V. CMS estimates the offset amount is \$7.8 billion; this amount is less than the estimated remedy amount.

CMS proposes to adjust payments for services to all providers made between 2018

and 2022. This calculated impact is solely related to the 340B Program adjustment made to hospital payment policy. Beginning with CY 2025, CMS proposes to reduce all payments for non-drug items and services by 0.5 percent (applied to the conversion factor) each year until the total offset amount is reached, estimated to be 16 years. By delaying implementation by 1 year, this allows the agency to finalize the methodology, calculate and publish rates in the CY 2025 proposed rule, and allow stakeholders time to review and comment. CMS believes the 0.5 percent reduction would be less burdensome to hospitals, especially rural entities, especially when there may be other factors impacting payments over the next several years. CMS sought comments on the proposed annual percentage reduction to the conversion factor and whether a different timeline could be used to offset budget neutrality.

CMS is proposing to exclude new hospitals enrolled in Medicare after January 1, 2018, so that they are not subject to the prospective rate reduction, which is predominantly designed to offset those non-drug item and service payments made during CY 2018 through CY 2022. These hospitals would be paid with a conversion factor if no remedy payment were needed and identified per their CMS certification number (CCN) effective date. CMS has provided a list of these entities, approximately 300, in Addendum BBB of the proposed rule.

The final MPFS and HOPPS rules are expected on or before November 1, 2023. This is when providers will find out if the various payment policies and regulatory updates were finalized as proposed or something different. As for the 340B Drug Discount Program, it is likely the final rule will be released prior to the end of 2023.

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