Highlights from the CY 2023 MPFS and HOPPS Proposed Rules

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It's that time of year again, digesting the thousands of pages produced by the Centers for Medicare & Medicaid Services (CMS) to share the agency's vision of healthcare spending for physicians, hospitals, ambulatory surgical centers, and office settings for the coming year. This year, the proposed rules were released separately: the Medicare Physician Fee Schedule (MPFS)[1] on July 8, 2022, and the Hospital Outpatient Prospective Payment System (HOPPS)[2] on July 15, 2022. Both rules outline how CMS is planning to transition from the public health emergency (PHE) and the provisions and waivers in response to the COVID-19 pandemic to more of "how it used to be" mixed in with a "new normal."

Below are several of the proposed key items that relate or impact oncology programs and providers. Note: Some payment impacts are outside CMS's authority to change. This includes the 2 percent sequestration reduction that was fully reimplemented on July 1, 2022, after suspension due to the PHE and the 4 percent reduction in payments due to the pay-as-you-go rule that is expected to begin Jan. 1, 2023. The pay-as-you-go decrease is due to the economic relief provided as part of the COVID-19 response and a way for the federal government to earn back monies. These reductions (−6 percent) apply to Medicare payments for each code and are added to the payment policies proposed by CMS for calendar year (CY) 2023.

Medicare Physician Fee Schedule

The MPFS provides the regulatory information and payment rates for all physicians across all practice settings. Stakeholders had 60 days from July 8, 2022, to submit comments to CMS on the proposed changes for CY 2023.

The conversion factor is the value multiplied to the assigned relative value units (RVUs) of physician work, practice expense, and malpractice of each code to determine the dollar amount of each code's payment. CMS proposed a conversion factor of $33.0775—a decrease of 4.5 percent from the CY 2022 conversion factor of $34.6062. In Table 1, right, CMS provided a breakdown of the proposed payment impacts to oncology specialties. This breakdown only reflects the impact to the estimated RVUs and does not reflect other changes, such as the 4.5 percent decrease to the conversion factor.

CMS proposed updates to the malpractice RVUs for next year; these were last updated in CY 2020 and are required to be updated every three years. Based on the malpractice or practice liability insurance data collected from all 50 states, CMS proposed changes to the risk index values that are used to calculate the malpractice RVUs at the code level. Malpractice RVUs reflect the risk of the primary specialty assigned to the service that performs the service. For CY 2023, the risk index value for hematology/oncology is proposed to decrease from 0.765 to 0.741 for years 2023 to 2025 and, for radiation oncology, CMS proposed an increase from 0.840 to 0.905 for years 2023 to 2025.

Evaluation and Management Codes

Effective Jan. 1, 2023, there will be updates to the next set of evaluation and management (E/M) codes. These codes are the "Other E/M" visits (inpatient and observation visits, emergency department visits, nursing facility visits, domiciliary or rest home visits, home visits, and cognitive impairment assessments). These codes exclude critical care services, yet they match the framework (e.g., medical decision making or time-based) of the outpatient and office E/M visits that changed in 2021. CMS proposed to accept and move forward with the American Medical Association (AMA) Current Procedural Terminology (CPT®) Editorial Panel changes, with a few minor exceptions. Changes to the "Other E/M" visit codes made by the AMA were released in early July 2022 and can be found online at ama-assn.org/system/files/2023-e-m-descriptors-guidelines.pdf.

CMS clarified its proposal to slightly amend the definitions of "initial" and "subsequent" in relation to E/M visits for inpatient services. The agency does not recognize subspecialties, as is outlined in the CPT manual, so it proposed the following language:[1]

- "An initial service would be defined as one that occurs when the patient has not received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the same specialty who belongs to the same group practice during the stay."
- "A subsequent service would be defined as one that occurs when the patient has received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the same specialty who belongs to the same group practice during the stay."

CMS also proposed three new Healthcare Common Procedure Coding System (HCPCS) codes to be used in place of the AMA created CPT code **993X0** for prolonged services. One code would be for hospital inpatient or observation care, one for nursing facilities, and one for home or residence. Starting in 2023, providers should use the below code to bill prolonged services for inpatient time-based visits with their Medicare beneficiaries:

Table 1. CY 2023 MPFS Estimated Impact on Total Allowed Charges by Setting

SPECIALTY	TOTAL NON-FACILITY /FACILITY	ALLOWED CHARGES (MILLIONS)	COMBINED IMPACT
Hematology/oncology	Total	$1707	−1%
	Non-facility	$1130	−2%
	Facility	$577	1%
Radiation oncology and radiation therapy centers	Total	$1609	−1%
	Non-facility	$1540	−1%
	Facility	$69	−1%

- **GXXX1**. Prolonged hospital inpatient or observation care evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes **99223**, **99233**, and **99236** for hospital inpatient or observation care evaluation and management services). Do *not* report **GXXX1** on the same date of service as any other prolonged service for evaluation and management (**99358**, **99359**, **993X0**). Do *not* report **GXXX1** for any time unit less than 15 minutes.

These new HCPCS codes would replace the existing CPT codes for inpatient prolonged services:

- **99356**. Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour. (List separately in addition to the code for inpatient or observation E/M service.)
- **99357**. Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; each additional 30 minutes. (List separately in addition to code for prolonged service.)

As with outpatient prolonged services, CMS did not agree with the AMA on how it counted time to meet the threshold for billing new codes. In addition, the prolonged service code **GXXX1** can only be used with the highest-level hospital inpatient or observation care visit codes (**99223**, **99233**, and **99236**) when the time-based method is used.

CMS proposed that the prolonged service period described by **GXXX1** begins 15 minutes after the total times (as established in the physician time file) for codes **99223**, **99233**, and **99236** have been met. Additionally, CMS proposed that the **GXXX1** prolonged code would be for a 15-minute increment, and the entire 15-minute increment must be completed to bill the code.

CMS also proposed that **GXXX1** would apply to face-to-face and non-face-to-face time spent on patient care within the survey time frame. For codes **99223** and **99233**, this would be time spent on the date of the patient encounter. For code **99236**, this would be time spent within three calendar days of the patient encounter.

CMS proposed to fully integrate E/M split (or shared) visits for new and established patients in 2024 (a one-year delay) to allow full acquaintance and implementation of the other E/M visit changes for healthcare providers.

Telehealth Post-PHE

The provisions and waivers that were implemented in response to the COVID-19 pandemic will continue for 151 days after the end of the PHE. As of the time of this writing, the PHE is scheduled to end on October 13, 2022. CMS reiterated that if any codes are not included in the telehealth list of services that are identified as continuing permanently or temporarily, as a category 3 telehealth service, they will end on day 152 after the PHE's end date. Specific to oncology, services to be removed include:

- **77427**. Radiation oncology physician management
- Initial inpatient E/M codes **99221**, **99222**, and **99223**
- Audio-only codes **99441**, **99442**, and **99443**.

With some exceptions, billing for telehealth services will return to pre-PHE guidelines and will no longer require the use of **modifier 95**. Instead, the appropriate **place of service code** (**02** or **10**) must be applied to process payment.

Another change is that telehealth visits will no longer be allowed for patients in their homes or anywhere outside of an originating site other than the statutory exceptions for diagnosis, evaluation, and treatment of mental health disorders; home dialysis and end-stage renal disease-related visits; and diagnosis, evaluation, and treatment of acute stroke symptoms.

Manufacturer Refunds for Discarded Single-Use Vial Amounts

Drugs and biological "drugs" are administered to patients in varying amounts; often, the amount administered is less than the total amount available in the drug's vial or package. Some of these drugs are only available in single-dose vials or single-dose packages. The U.S. Food and Drug Administration (FDA)-approved labeling for a drug packaged in a single-dose container typically states that any extra amount of the drug remaining after a dose is administered must be discarded. Based on this language, under Part B, Medicare established that any unused

and/or discarded amounts from a single-dose vial or single-dose package would be paid when reported on the claim with use of **modifier JW**. Note: **modifier JW** cannot be used with drugs that are not separately paid, such as drugs packaged into outpatient hospital services or other designated settings.

Section 90004 of the Infrastructure Investment and Jobs Act[3] requires manufacturers to provide a refund to CMS for certain discarded amounts of a refundable single-dose container or single-use package drug. The refund amount is the amount of the discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of the total charges for the drug in a given calendar quarter. CMS clarified that refundable single-dose vials or single-dose packages do not include radiopharmaceuticals, imaging agents, certain drugs requiring filtration, and certain new drugs. To accomplish the requirements of the Act, CMS proposed the following:[3]

- Use **modifier JW** (or if another modifier is used or added in the future for the same data) to identify discarded billing units of a billing and payment code to calculate the refund amount.
- For dates of service on or after Jan. 1, 2023, **modifier JW** will be required on claims for all single-dose container or single-use drugs when any amount is discarded, as part of CMS' current policy.
- Use **modifier JZ** on billing claims to attest there was no discarded amount from the single-dose vial or single-use package that is normally paid under Part B with **modifier JW**.
- The definition for refundable single-dose container or single-use package drug would apply "to drugs paid under Medicare Part B (that is, under any payment methodology) that are described as being supplied in a 'single-dose' container or 'single-use' package based on FDA-approved labeling or product information. This definition also includes drugs described in FDA-approved labeling as a 'kit' that is intended for a single dose or single use."[3]
- Excluded drugs would be radiopharmaceuticals, imaging agents, drugs requiring filtration during the preparation process, and drugs approved on or after the Act's date of enactment (Nov. 15, 2021), for which payment under Part B has been made for fewer than 18 months.
- Exclusion of drugs requiring filtration during their preparation process specifically pertains to those in which the dosing and administration instructions that are included in the labeling require filtration during the drug preparation process, prior to dilution and administration, and that require any unused portion be discarded after the filtration process be discarded.
- Annual reports would be sent to drug manufacturers no later than Oct. 1 of each year that include data from second, third, and fourth quarters of the previous year and the first quarter of the current year.
- Refunds by drug manufacturers would be due no later than Dec. 31 of the year in which the annual report was delivered.
- Establishment of a dispute resolution process, civil monetary penalties, and periodic review of Part B medication claims to ensure **modifier JW**, **modifier JZ** (if finalized), and discarded drug amounts are billed appropriately as part of the already developed claims audit policy and process.

Hospital Outpatient Prospective Payment System

The HOPPS provides the regulatory information and payment rates for facility-based settings, outpatient hospitals, and ambulatory surgical centers. Stakeholders had 60 days from July 15, 2022, to submit comments to CMS on the proposed changes for CY 2023.

CMS proposed a 2.7 percent increase to the Outpatient Department fee schedule. The agency estimates that total payments to HOPPS from providers will be approximately $86.2 billion, an increase of approximately $6.2 billion when compared to CY 2022 HOPPS payments. However, due to a June 15, 2022, U.S. Supreme Court ruling related to the 340B Drug Discount Program, CMS provided an alternate payment file for CY 2023 HOPPS rates, which takes into account the shift from average sales price (ASP) −22.5 percent to ASP +6 percent.

Procedures Assigned to New Technology APC Groups for CY 2023

When new technology is assigned a billing code, it can be difficult for CMS to establish a payment rate because there are no claims data to determine provider utilization and costs. To meet this challenge, CMS created New Technology Ambulatory Payment Classifications (APCs), which are like pass-through payments for new drugs, biologicals, radiopharmaceuticals, and devices. The new technology is assigned a temporary APC until claims data is available. Typically, this assignment is a minimum of two years, but it can be less if data is available sooner. Once there are sufficient data, the new technology is moved to a clinically appropriate APC.

For example, scalp cooling is a new technology that became effective July 1, 2021, and is used to describe initial measurement and calibration of a scalp cooling device for patients' use during chemotherapy administration to prevent hair loss. The scalp cooling device is included in Medicare's national coverage determination (NCD) policy, specifically, **NCD 110.6** (scalp hypothermia during chemotherapy to prevent hair loss). The scalp cooling cap is classified as a supply and is not paid separately under HOPPS. CMS has received comments that indicate that there are substantial resource costs ($1,900 to $2,400) for cap calibration and fitting. The Category 3 code **0662T** is billable once per chemotherapy session, which CMS interprets to be once per course of chemotherapy. Scalp cooling was new under the CY2022 HOPPS, so there are no claims data yet for this technology. As such, CMS proposed to continue assigning scalp cooling to a New Technology APC for CY 2023.

Payments of Drugs, Biologicals and Radiopharmaceuticals

CMS proposed the following payment policies for drugs, biologicals, and radiopharmaceuticals:

- Packaging of drugs and biologicals estimated at a per day administration cost less than or equal to $135. (Note: In CY 2022, this amount was set at less than or equal to $130.)
- Continuing to separate payment for items with an estimated per day cost greater than $135 except for diagnostic radiopharmaceuticals; contrast agents; anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies or devices when used in a surgical procedure.

- Continuing the policy of making packaging determinations on a drug-specific basis rather than by HCPCS code for those codes that describe the same drug or biological in different dosages.
- Continuing the policy to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product approved for a reference product.
- Continuing to provide payment for diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on ASP methodology, because CMS considers these to be drugs under HOPPS.

340B Drug Discount Program

In the CY 2018 HOPPS final rule, CMS finalized the policy to pay for drugs purchased under the 340B Drug Discount Program at ASP −22.5 percent. (Note: This payment policy did *not* include drugs with pass-through payment status or vaccines.) This rate was significantly different than the previous rate of ASP +6 percent. Since this payment policy was updated in CY 2018, there has been significant litigation that has resulted in varying decisions, some which favored the plaintiff and some which favored the defendant (CMS). In response to these rulings, the payment policy for the 340B Drug Discount Program has had some back-and-forth adjustments between the ASP +6 percent and ASP −22.5 percent rates.

On June 15, 2022, the U.S. Supreme Court filed a decision in the *American Hospital Association v. Becerra*, No. 20-1114, 2022 WL 2135490 case.[4] The court reversed the decision of the U.S. Court of Appeals for the District of Columbia Circuit, citing that Health and Human Services secretary may *not* vary payment rates for drugs and biologicals among groups of hospitals in the absence of having conducted a survey of hospitals' acquisition costs. Though the court's decision concerned CY 2018 and CY 2019 payments, the decision has implications for CY 2023.

Utilizing the separately paid line items with modifier **JG** (the modifier used to identify drugs purchased under the 340B Drug Discount Program) in the CY 2021 claims data available for HOPPS rate-setting, the estimated payment differential would be an increase of approximately $1.96 billion in HOPPS drug payments. To ensure budget neutrality, CMS would apply this offset and decrease HOPPS payments by factoring in a 0.9596 adjustment for a revised CY 2023 conversion factor of $83.279. In comparison, CMS originally proposed the CY 2023 conversion factor, with payments for 340B drugs at ASP −22.5 percent, as $86.785. CMS provided 340B alternate payment files for CY 2023, which reflect a decrease in values; the files do not reflect how payments would be adjusted for CYs 2018 to 2022, which must also be paid back to hospitals. CMS is seeking comments on how to incorporate these additional adjustments for the aforementioned years.

The following is provided directly from a section of the CY 2023 HOPPS proposed rule titled *Summary of Major Provisions*, in which CMS summarizes the issue and request for comments:[2]

"For CY 2023, we formally propose at this time to continue our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs and biologicals, including when furnished in nonexcepted off-campus PBDs [provider-based departments] paid under the [M]PFS. This proposal is in accordance with the policy choices and calculations that CMS made in the months leading up to publication of this proposed rule before the [U.S.] Supreme Court issued its decision in American Hospital Association v. Becerra (Docket 20-1114). However, we note that, in light of the Supreme Court's recent decision in American Hospital Association v. Becerra, we fully anticipate applying a rate of ASP + 6 percent to such drugs and biologicals in the final rule for CY 2023 and making a corresponding decrease to the conversion factor consistent with the [H]OPPS statute and our longstanding policy that this adjustment is made in a budget neutral manner. We are still evaluating how to apply the Supreme Court's recent decision to prior calendar years. In that decision, the Court summarized the parties' arguments regarding budget neutrality and stated that, '[a]t this stage, we need not address potential remedies.' We are interested in public comments on the best way to craft any potential remedies affecting cost years 2018 [to] 2022 given that the Court did not resolve that issue."

The CY 2023 final rules are expected to be released on or before Nov. 1, 2022. This is when we will find out whether the various payment policies and regulatory updates were finalized as proposed or something different. Outside of CMS's rulemaking, it is expected there may be some changes of other payment decreases, which the agency does not have the authority to change. It is quite possible the provider community may not know for certain until the end of December what reimbursement rates will be in place starting Jan. 1, 2023.

Lastly, as of the writing of this article, there is still no word on the status of the Radiation Oncology Model; we are still awaiting the outcome of the proposal due to a delay. OI

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