Highlights from the CY 2022 MPFS and HOPPS Proposed Rules

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Over the past few months there has been a flurry of activity from the Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS), and Health Resources and Services Administration (HRSA), including the release of the CMS calendar year (CY) 2022 proposed rules for the Medicare Physician Fee Schedule (MPFS) and Hospital Outpatient Prospective Payment System (HOPPS), extension of the public health emergency by HHS through Oct. 18, 2021, and HRSA notification of post-payment reporting as part of the Provider Relief Fund (PRF). Below is a summary of how these notifications may impact oncology.

MPFS Proposed Changes

On July 13, 2021, CMS issued the proposed MPFS rule for CY 2022.[1] Comments must be submitted to CMS by 5:00 PM EST on Sept. 15, 2021.

Payment Rates

For CY 2022, CMS is reversing the 3.75 percent increase outlined as part of the Consolidated Appropriations Act of 2021, which reversed the 10.2 percent cut finalized to the conversion factor for CY 2022. Removing this and using a conversion factor of 33.6319, CMS applied a budget neutrality factor of −0.14 percent. This results in a proposed conversion factor of $33.5848, which is slightly lower than the conversion factor for CY 2020.

Table 1, page 8, outlines the combined impact of the proposed relative value unit (RVU) changes for CY 2022 by specialty. The RVU cuts specific to the practice expense values are due to the adjustment of labor values and the final year of the four-year supply and equipment updates. According to CMS, stakeholders requested updated labor values to correspond with updated supply and equipment values. Clinical labor rates were last updated in CY 2002, and the agency is proposing to update the values for CY 2022 using CY 2019 survey data from the Bureau of Labor and Statistics and other supplementary data when these data are not available. Note: an increase in labor values is indicated for all of the labor types reviewed by CMS and because the values are maintained in a budget-neutral manner, increases for one specialty or one code (or code set) are possible only because it was taken or adjusted from another specialty or code (or code set).

Specifically, for some specialties, like family practice, the labor has a higher-than-average share of the direct costs, whereas for other specialties, such as radiation oncology, the labor has a lower-than-average share of the direct costs. Specialties with a higher share of labor costs are proposed to receive increased payments for their services, whereas specialties that have lower direct costs associated to clinical labor will see decreases in payment for their services.

CMS reviewed the anticipated impact that these labor value changes would have on various specialties and the payment for their services. The agency indicated that when updates to payment methodology result in significant shifts in payments, it does consider the possibility and impact of phasing in the changes. Typically, this phase-in is done over a four-year transition, similar to when the supply and equipment value changes were implemented in CY 2019 and spread over a four-year timeline. However, CMS is concerned that a phased-in transition would result in the need to use outdated clinical labor pricing for the time the transition is taking place because each year would use partial new values and older values to calculate payment. CMS estimates that the effect of the labor pricing update alone is as follows:

- Radiation oncology: −4 percent
- Hematology/oncology: −2 percent.

Changes to E/M Services: Split (or Shared) Visits

CMS indicated that when the American Medical Association adopted new guidelines for outpatient and office setting evaluation and management (E/M) visits, CMS also adopted these changes. In the months since implementation, the agency indicated a need to clarify or adjust previous guidelines to align more fully with the updates.

Specific to split (or shared) visits, CMS indicated that these guidelines do not address:

- Who to bill when the visit (and services) are performed by different practitioners.
- Whether a substantive portion must be performed by the billing practitioner.
- Whether practitioners must be in same group.
- The setting where the split (or shared) visits may be furnished to be billed.

CMS is proposing to define a split (or shared) visit as an E/M visit performed (split or

Table 1. CY 2022 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) SPECIALTY	(B) ALLOWED CHARGES (MIL)	(C) IMPACT OF WORK RVU CHANGES	(D) IMPACT OF PRACTICE EXPENSE RVU CHANGES	(E) IMPACT OF MP RVU CHANGES	(F) COMBINED IMPACT*
Hematology/ oncology	$1,737	0%	-2%	0%	-2%
Radiation oncology and radiation therapy	$1,660	0%	–5%	0%	–5%

The decrease in the conversion factor does result in a decrease in many specialties and their proposed impact; however, CMS has also applied additional decreases to many of the practice expense values, which reflect a deeper cut to certain specialties, such as interventional radiology, radiation oncology, vascular surgery, and oral/maxillofacial surgery.

*Column F may not equal the sum of columns C, D, and E due to rounding.

shared) by both a physician and non-physician practitioner (NPP) who are in the same group in accordance with applicable laws and regulations. The visit is provided in a facility setting in which payment for services furnished incident to is prohibited. In the non-facility setting, when the physician and NPP each perform components of the visit, it can be billed under the physician if the incident-to criteria are met. The services are provided in accordance with applicable laws and regulations; specifically, either the physician or NPP could bill the payer directly for the visit in the facility setting, rather than bill as a split (or shared) visit. CMS is also proposing to allow for split (or shared) visits to be billed for both new and established E/M patient visits.

CMS is clarifying that only the physician or NPP who performs the substantive portion of the split (or shared visit) can bill for the visit. CMS is defining "substantive portion" to mean more than half of the total time spent by the physician or NPP performing the visit. Due to the need to determine the amount of time spent by each clinician, CMS is recommending that documentation of time be included in the patient note, even if the medical decision-making method is selected to code the visit. In addition, the clinician who performs the substantive portion of the visit should be the one to sign and date the patient note, but documentation should include the names and credentials of both clinicians. Once the total times between the physician and NPP are added together, the clinician with the majority of the time will bill the visit based on the total time documented. CMS has also proposed that prolonged services can be billed in addition to the visit when the time-based method is used with the total time between the two clinicians.

The agency is proposing a list of services that would count toward the total time for determining the substantive portion, including:

- Preparing to see the patient (for example, review of tests)
- Obtaining and/or reviewing separately obtained history
- Performing a medically appropriate examination and/or evaluation
- Counseling and educating the patient, family, and/or caregiver
- Ordering medications, tests, or procedures
- Referring and communicating with other healthcare professionals (when not separately reported)
- Documenting clinical information in the electronic or other health record
- Independently interpreting results (not separately reported)
- Communicating results to the patient, family, and/or caregiver
- Care coordination (not separately reported).

CMS identified items that would *not* count toward time spent in a visit:

- Performance of other services that are reported separately
- Travel
- Teaching that is general and not limited to discussion that is required for the management of a specific patient.

CMS is also proposing to create a modifier for billing purposes to identify a visit as a split (or shared) visit. This will allow Medicare to collect data on the frequency and quality of visits provided in part by NPPs but paid to physicians for the full rate.

If the physician and NPP are not in the same group, they would each be expected to bill independently based on the full E/M criteria for the work provided. If neither practitioner meets the criteria to bill a visit, modifier 52 for reduced services cannot be applied to the E/M visit codes. In this scenario, neither professional would be able to bill for the visit.

Payment for the Services of Teaching Physicians

Stakeholders requested guidance on how time spent by residents should be counted when selecting the appropriate E/M office visit level. Section 1842(b) of the Social Security Act specifies, "In the case of physicians' services furnished to a patient in a hospital with a teaching program, the Secretary shall not provide payment for such services unless the physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which payment is sought. Regulations regarding MPFS payment for teaching physician services."

CMS is proposing that when total time is used to determine the appropriate E/M office visit level, only the time the teaching physician was present can be included. Because Medicare already makes payment for the program's share of the resident's involvement, the agency does not feel that it would be appropriate to count the resident time toward the total time. Only the time of the teaching physician would count.

HOPPS Proposed Changes

On July 19, 2021, CMS issued the proposed rules for HOPPS for CY 2022.[2] Comments must be submitted to CMS by 5:00 PM EST on Sept. 17, 2021.

Payment Rates

Because of the COVID-19 public health emergency (PHE) and pandemic, CMS is proposing to use CY 2019 claims data for rate setting rather than CY 2020 claims date due to the significant impact in utilization of services. Based on this, CMS is proposing a 2.3 percent increase to the outpatient department fee schedule.

Payments of Drugs, Biologicals, and Radiopharmaceuticals

CMS is proposing to continue the payment policy to pay for drugs purchased under the 340B Drug Program at the average sales price (ASP) –22.5 percent. The agency is proposing to continue to exempt rural sole community hospitals, children's hospitals, and prospective payment system-exempt cancer hospitals from this policy.

Due to the proposal to use CY 2019 claims data for rate setting, CMS is proposing to extend, for up to four quarters, an equitable adjustment for 27 drugs and biologicals and one device, which would expire pass-through status at various quarters in CY 2022 and extend pricing through the end of CY 2022.

The agency is proposing to continue the ASP+6 percent payment policy for all drugs, biologicals, and therapeutic radiopharmaceuticals granted pass-through status and update the list on a quarterly basis.

CMS is proposing to continue the packaging threshold for drug administration at less than or equal to $130; this is the same threshold from CYs 2020 and 2021. CMS is proposing to make drug packaging determination on a drug-specific basis rather than on a Healthcare Common Procedure Coding System (HCPCS) code-specific basis for HCPCS codes that describe the same drug with different dosages.

The agency is proposing to continue the payment policy for biosimilar biologicals, with pass-through status eligibility made for the biosimilar biological product and not the reference product. CMS is proposing to continue paying for biosimilar biologicals purchased under the 340B Drug Program at ASP–22.5 percent of the biosimilar biological, not the reference product, which is a continuation of the CY 2021 policy.

CMS is proposing to continue to establish payment rates for blood and blood products using its blood-specific cost-to-charge ratio methodology, which has been the standard since CY 2005.

COVID-19 Waivers and Extensions

CMS is seeking comments on several waivers and extensions as part of the COVID-19 PHE. Specifically, the agency is looking for feedback on whether certain provisions, which were waived or extended during the COVID-19 PHE, should continue for a limited period of time or permanently, including:

- Hospital staff furnishing services remotely to beneficiaries in their homes through use of communications technology.
- Providers furnishing services in which the direct supervision requirement for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services was met by the supervising practitioner being available through audio and video real-time communications technology.
- The need for specific coding and payment to remain available under HOPPS for specimen collection for COVID-19.

RO Payment Model

Below is a summary of the changes CMS is proposing to the Radiation Oncology (RO) Model. For additional information and resources, visit the RO Model website at: innovation.cms.gov/innovation-models/radiation-oncology-model. CMS is proposing a new timeline for the RO Model to extend five years, beginning Jan. 1, 2022, and running through Dec. 31, 2026—pending no legal or additional congressional intervention. The agency also indicated that no new episodes of care could begin after Oct. 3, 2026, to allow for treatment completion prior to the scheduled end date on Dec. 31, 2016.

RO Model participants will be selected using randomly selected core-based statistical areas. CMS is proposing that organizations that are part of the Pennsylvania Rural Health Model will only be excluded from the RO Model for the time they are participating in the Pennsylvania Model. Once a hospital outpatient department is no longer participating in the Pennsylvania Model and if they are in a selected core-based statistical area (or ZIP code), they will be expected to participate in the RO Model.

CMS is proposing to remove any incentive for RO Model participants who change their taxpayer identification number (TIN) or CMS certification number (CCN) to become eligible for the low-volume opt-out. To do this, CMS is proposing that an entity would not be eligible to opt out if its legacy TIN or legacy CCN was used to bill Medicare for 20 or more episodes or RO episodes, as applicable, of radiation therapy services in the two years prior to the corresponding performance year in a selected core-based statistical area. The agency is proposing that it would include episodes and RO episodes associated with a model participant's current CCN or TIN, as well as any attributed to the participant's legacy CCN(s) or TIN(s).

CMS is proposing a change to the number of cancer types included in the RO Model. Initially 16 cancer types were finalized, but after consideration and stakeholder feedback, the agency is proposing to remove liver diagnosis from these cancer types. CMS indicated that liver cancer and the radiation therapy services used to treat it are evolving and varied. Various randomized trials do not include radiation therapy as a first-line therapy. CMS is proposing to only include 15 cancer types.

CMS is also proposing to remove brachytherapy services from the list of included radiation therapy services as part of the RO Model. This proposal is due to stakeholder feedback indicating that because of the bundled payments, there could be decreased utilization where combined external beam and brachytherapy would be clinically indicated, specifically for cervical and prostate cancers. There is belief that the bundling will ultimately result in the disincentive to refer patients to another radiation oncologist for treatment when the RO Model participant does not or cannot deliver brachytherapy services themselves.

CMS is also seeking comments on whether intraoperative radiotherapy should be included in the RO Model. CMS received stakeholder feedback requesting that this service be added. However, because it is only performed in the hospital setting, it is not setting agnostic, and it is limited to certain cancer types, CMS has concerns about its inclusion.

Table 2, right, lists the HCPCS codes assigned per cancer type as well as the national base rates proposed to begin Jan. 1, 2022. Rates are based on a weighted calculation from three years of claims data prior to the performance year.

CMS expects the RO Model to meet the criteria to be an advanced APM (alternative payment model) and merit-based incentive payment system APM in performance year 1, beginning Jan. 1, 2022. Final CMS determinations of advanced APMs and merit-based incentive payment system APMs for the 2022 performance period will be announced via the Quality Payment Program website at: qpp.cms.gov/.

HRSA Provider Relief Fund

On June 11, 2021, HHS sent a notice to HRSA Provider Relief Fund recipients to inform them about the data elements they are required to report in the post-payment reporting process.[3] As part of the Coronavirus Aid, Relief, and Economic Security (CARES)

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Table 2. HCPCS Codes Assigned Per Cancer Type and National Base Rates

RO MODEL-SPECIFIC CODES	PROFESSION OR TECHNICAL	INCLUDED CANCER TYPE	NATIONAL BASE RATE
M1072	Professional	Anal cancer	$3,104.11
M1073	Technical	Anal cancer	$16,800.83
M1074	Professional	Bladder cancer	$2,787.24
M1075	Technical	Bladder cancer	$13,556.06
M1076	Professional	Bone metastases	$1,446.41
M1077	Technical	Bone metastases	$6,194.22
M1078	Professional	Brain metastases	$1,651.56
M1079	Technical	Brain metastases	$9,879.40
M1080	Professional	Breast cancer	$2,059.59
M1081	Technical	Breast cancer	$10,001.84
M1082	Professional	CNS tumor	$2,558.46
M1083	Technical	CNS tumor	$14,762.37
M1084	Professional	Cervical cancer	$3,037.12
M1085	Technical	Cervical cancer	$13,560.15
M1086	Professional	Colorectal cancer	$2,508.30
M1087	Technical	Colorectal cancer	$12,200.62
M1088	Professional	Head and neck cancer	$3,107.95
M1089	Technical	Head and neck cancer	$17,497.16
M1094	Professional	Lung cancer	$2,231.40
M1095	Technical	Lung cancer	$12,142.39
M1096	Professional	Lymphoma	$1,724.07
M1097	Technical	Lymphoma	$7,951.09
M1098	Professional	Pancreatic cancer	$2,480.83
M1099	Technical	Pancreatic cancer	$13,636.95
M1100	Professional	Prostate cancer	$3,378.09
M1101	Technical	Prostate cancer	$20,415.97
M1102	Professional	Upper GI cancer	$2,666.79
M1103	Technical	Upper GI cancer	$14,622.66
M1104	Professional	Uterine cancer	$2,737.11
M1105	Technical	Uterine cancer	$14,156.20

National base rates are proposed to begin Jan. 1, 2022; rates are based on a weighted calculation from three years of claims data prior to the performance year. CNS = central nervous system; GI = gastrointestinal.

Table 3. Summary of PRF Reporting Requirements

	PAYMENT RECEIVED PERIOD (PAYMENTS EXCEEDING $10,000 IN AGGREGATE RECEIVED)	DEADLINE TO USE FUNDS	REPORTING TIME PERIOD
Period 1	April 10, 2020-June 30, 2020	June 30, 2021	July 1, 2021-Sept. 30, 2021
Period 2	July 1, 2020-Dec. 31, 2020	Dec. 31, 2021	Jan. 1, 2022-March 31, 2022
Period 3	Jan. 1, 2021-June 30, 2021	June 30, 2022	July 1, 2022-Sept. 30, 2022
Period 4	July 1, 2021-Dec. 31, 2021	Dec. 31, 2022	Jan. 1, 2023-March 31, 2023

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Act and the Paycheck Protection Program and Health Care Enhancement Act, monies were allocated to be distributed to healthcare providers as part of the Provider Relief Fund.

If determined eligible, qualified providers of healthcare services and support could receive relief payments for healthcare-related expenses for lost revenue due to COVID-19. These payments do not need to be paid back, but if recipients received one or more payments exceeding $10,000 in the aggregate during a payment receipt period, they must submit reporting requirements as agreed to in the terms and conditions of the specific funding.[4] Because each distribution has its own terms and conditions, providers must review the distribution they received to understand any specifics related to their agreement. Table 3, above, outlines the four different periods of payments received, the deadline to use the funds, and the reporting time period. Healthcare providers must report how they used the funds received if they reach the threshold amount. Reporting is submitted in consolidated reports per the normal basis of accounting. Per the notice, data are reported in the following order:

1. Interest earned on PRF payment(s)
2. Other assistance received
3. Skilled nursing facility and nursing home infection control distribution payments use (if applicable)
4. General and other targeted distribution payments
5. Net unreimbursed expenses attributable to coronavirus
6. Lost revenue reimbursement.

Healthcare providers who received between $10,001 and $499,999 in aggregated relief payments during each payment receipt period are required to report on two categories of data: 1) general and administrative expenses and 2) healthcare-related expenses. Those receiving $500,000 or more are required to provide more detail in the two categories, including mortgage and rent, fringe benefits, utilities, supplies and equipment purchased, information technology, and other healthcare-related expenses.

The use of the Provider Relief Fund is specific to costs incurred to prevent, prepare for, and respond to COVID-19. Providers are expected to ensure that documentation is present and supports how the funds received were used. According to the HHS website, the burden of proof is on the provider to ensure that the documentation supports how the monies were used and that monies were used as intended as part of the terms and conditions to which the provider agreed when receiving the funds.[5] The HHS HRSA Provider Relief Fund Portal is active and open for reporting at: prfreporting.hrsa.gov/s. If providers are not already registered, they can do so at the portal link. Several resources are available on the portal, which can be accessed without logging in:

- Portal FAQs: prfreporting.hrsa.gov/HRSA_FileRender?name=PortalFAQs
- Registration User Guide: prfreporting.hrsa.gov/HRSA_FileRender?name=RegistrationUserGuide
- Reporting User Guide: prfreporting.hrsa.gov/HRSA_FileRender?name=ReportingUserGuide
- Portal Worksheets: prfreporting.hrsa.gov/HRSA_FileRender?name=PortalWorksheets.

As oncology providers continue to work through 2021, it is not too early to begin preparing for 2022. The many waivers and extensions exercised for the past nearly two years are now coming due in different ways, and it will be interesting to see how all of this will play out as the impact for some may be more burdensome than it is for others. OI

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