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November 10, 2021

CMS Finalizes the Medicare Hospital Outpatient Prospective Payment System for 2022

The Big Picture

On November 2, the Centers for Medicare & Medicaid Services (CMS) released the final rule *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model*, setting new outpatient Medicare payment policy for calendar year (CY) 2022, effective January 1.

The Medicare Outpatient Prospective Payment System (OPPS) establishes a system of reimbursement for services delivered by hospital outpatient departments, while the Ambulatory Surgical Center Payment System is a separate but related fee schedule of facility charges for surgical procedures that CMS has determined do not pose a risk to beneficiary safety when performed in an ambulatory surgical center (ASC). In this rule:

- CMS is finalizing an increase in payment rates under the OPPS by an outpatient department fee schedule factor of 2.0%.
- Citing an observed "high rate of hospital noncompliance" with new price transparency rules, CMS is increasing penalties for noncompliance and clarifying inappropriate information display practices.
- CMS is continuing all its current payment policies for biosimilars.
- CMS is maintaining its current policy of reimbursing hospitals for 340B-purchased drugs and biologicals (other than drugs with pass-through payment status and vaccines) at a lower rate than non-340B-purchased drugs.
- CMS is making a one-time equitable adjustment under Section 1833(t)(2)(E) to continue separate payment for the remainder of CY 2022 for devices, drugs, and biologicals with pass-through status that expires between December 31, 2021, and September 30, 2022. There are 27 drugs and biologicals that fall into this category.
- CMS is reversing the policy finalized in last year's OPPS Final Rule to eliminate the inpatient-only (IPO) list over time and remove 298 services from the list in CY 2021.
- CMS is finalizing its decision to launch the long-delayed Radiation Oncology Model on January 1, 2022.

In the proposed rule, CMS had solicited comments on whether several temporary payment policies should continue after the COVID-19 public health emergency (PHE). CMS did not

address this situation in the final rule. It acknowledged the comments and deferred the issue to future rule making.

OPPS Annual Payment Update

CMS is finalizing payment rate increases under the OPPS by an outpatient department fee schedule factor of 2.0%, which is less than the proposed increase of 2.3%. CMS estimates that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case mix) for CY 2022 would be $82.1 billion, an increase of $5.9 billion from estimated CY 2021 payments. CMS will continue to implement the statutory 2.0% reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9804 to the OPPS payments and copayments for all applicable services. Due to the COVID-19 PHE, CMS will use CY 2019 claims data instead of CY 2020 data to set OPPS and ASC payment system rates.

Payment of Drugs, Biologicals, and Radiopharmaceuticals

OPPS Payment for Non-packaged Drugs and Biologicals Without Pass-Through Status. CMS is finalizing its proposal to maintain the packaging threshold for establishing separate Ambulatory Payment Classifications (APCs) for drugs and biologicals at $130 unless the drugs or biologicals are policy-packaged, such as radiopharmaceuticals. Separately payable drugs and biologicals will continue to be paid at average sales price (ASP) plus 6% (prior to sequestration).

OPPS Payment for Biosimilars. CMS is continuing its current payment policies for biosimilars. This includes allowing all biosimilar products—and not just the first biosimilar product for a reference product—as eligible for pass-through payment. Please see the separate 340B section below for more detail on reimbursement for biosimilars that are 340B drugs.

340B Drug Discount Program

CMS is finalizing its proposal to maintain its current policy of reimbursing hospitals for drugs and biologicals purchased under Section 340B of the federal Public Health Service Act at a lower rate than applies to drugs and biologicals that are not purchased under Section 340B.

Under its current policy, which was implemented beginning in 2018, CMS reimburses for 340B-purchased drugs and biologicals at ASP minus 22.5%, rather than ASP plus 6%. The policy applies to separately payable drugs and biologicals (other than drugs with pass-through payment status and vaccines), and includes drugs and biologicals furnished in nonexcepted off-campus provider-based departments paid under the Medicare Physician Fee Schedule (MPFS). As noted in the section above, this also includes continuing payment for a non-pass-through biosimilar acquired under the 340B program to be the biosimilar's ASP minus 22.5% of the biosimilar's ASP (including when provided in nonexcepted off-campus provider-based departments paid under the MPFS).

Finally, CMS is finalizing its proposal to continue requiring that hospitals use modifiers to identify 340B-acquired drugs. As is currently the case, rural sole community hospitals, OPPS-exempt cancer hospitals, and children's hospitals are exempted and will continue to be reimbursed for 340B drugs at ASP plus 6%. While recognizing that the 340B drug payment rate is currently subject to litigation before the Supreme Court, CMS stated that it believes its 340B drug payment policy is consistent with federal law, and that even though litigation is pending, CMS believes maintaining the current payment policy is appropriate in order to maintain consistent and reliable payment. CMS also reiterates that it believes the current payment rate of ASP minus 22.5% represents the minimum discount that 340B covered entities receive.

Equitable Adjustment for Device Category, Drugs, and Biologicals With Expiring Pass-Through Status

CMS is finalizing a one-time equitable adjustment (under Section 1833(t)(2)(E) of the Social Security Act) to continue separate payment for the remainder of CY 2022 for devices, drugs, and biologicals with pass-through status that expires between December 31, 2021, and September 30, 2022. There are 27 drugs and biologicals that fall into this category. In particular, separate payment would be made for a full year for the six drugs for which pass-through status will expire on December 31, 2021; for three quarters for the 12 drugs and biologicals for which pass-through status will expire on March 31, 2022; for two quarters for the seven drugs for which pass-through status will expire on June 30, 2022; and for one quarter for the two drugs for which pass-through status will expire on September 30, 2022. CMS proposes this adjustment to ensure that it has full claims data from CY 2021 with which to set payment rates for CY 2023. As noted above, CMS believes that because of the PHE, the CY 2020 claims data may not be optimal for rate setting.

In making this payment adjustment, CMS proposes to maintain the same pass-through payment amount currently made in CY 2021 into CY 2022. This means that for products where payments would have been packaged (i.e., below the cost threshold or "policy" packaged), the separate pass-through payment will continue at ASP plus 6% (prior to sequestration). CMS will not apply the reduced amount of ASP minus 22.5% to pass-through drugs and biologicals acquired under 340B.

Packaging Policy for Non-opioid Pain Management Treatments

CMS is finalizing its proposal making a non-opioid pain management drug or biological that functions as a surgical supply in the ASC setting eligible for separate payment when it is approved by the FDA and indicated for pain management or as an analgesic, and with a per-day cost above the OPPS/ASC drug packaging threshold, beginning January 1, 2022. Accordingly, CMS finalized its proposal to continue separate payment in the ASC setting in CY 2022 for the two products (Exparel® and Omidria®) currently receiving separate payment under this policy since they meet the proposed criteria. CMS notes that separate payment for non-opioid pain

management drugs or biologicals that function as a surgical supply is appropriate in the ASC setting because CMS previously observed a decline in utilization when payment for such drugs or biologicals was packaged with the surgical procedure.

CMS finalized its proposal to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting. CMS explains that since utilization of non-opioid pain management drugs continues to increase year after year in the hospital outpatient department setting, where payment for these non-opioid alternatives is packaged with the payment for the associated surgical procedure, there is no conclusive evidence that the OPPS packaging policy has created financial incentives to use opioids instead of evidence-based non-opioid alternatives for pain management.

Hospital Outpatient Quality Reporting Program

CMS is finalizing several changes to the Hospital Outpatient Quality Reporting (OQR) Program, including to:

- **Adopt three new measures**, including (1) *COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)* (NQF #0431), beginning with the CY 2022 reporting period; (2) *Breast Screening Recall Rates*, beginning with the CY 2022 reporting period; and (3) *ST Segment Myocardial Infarction (STEMI) electronic clinical quality measure (eCQM)*, beginning as a voluntary measure with the CY 2023 reporting period and continuing as a mandatory measure beginning with the CY 2024 reporting period.

- **Make the reporting of two voluntary or suspended measures mandatory**, including (1) *Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures (OP–37a–e)*, beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination, and (2) *Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31/NQF #1536)*, beginning with mandatory reporting for the CY 2025 reporting period/CY 2027 payment determination instead of the CY 2023 reporting period/CY 2025 payment determination as was initially proposed.

- **Remove two measures**, including *Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department (ED) Arrival (OP-2)* and *Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP-3)*, effective with the CY 2023 reporting period.

Stakeholder Input on Health Equity in the Hospital OQR Program. CMS identified six priority measures included in the Hospital OQR Program as candidate measures for disparities reporting stratified by dual eligibility, including:

- MRI Lumbar Spine for Low Back Pain (OP-8)
- Abdomen CT – Use of Contract Material (OP-10)
- Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery (OP-13)
- Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (OP-32)
- Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy (OP-35)
- Hospital Visits after Hospital Outpatient Surgery (OP-36)

In the upcoming year, CMS intends to begin confidential reporting for some, though it does not say which, of the aforementioned measures stratified by dual eligibility status. Following potential confidential reporting using dual eligibility as an indicator of social risk, CMS plans to explore the possibility of further expanding stratified reporting of these measures to include race and ethnicity.

CMS is also planning to confidentially report outcome disparity results to facilities in spring of 2022 based on an algorithm that indirectly estimates beneficiary race and ethnicity using existing administrative and census-linked data where results are technically feasible, meaningful, and statistically reliable. However, any potential future proposal to publicly display the disparity results on Care Compare would be made through future rulemaking.

In the proposed rule, CMS had sought input on ideas to revise the Hospital OQR Program to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for facilities, providers, and patients, and developed the above approach in response to information received.

Hospital Price Transparency

CMS is moving forward with its plan to increase the penalties imposed on hospitals that fail to comply with new regulations requiring price transparency.

A CMS final rule, which was issued in 2019 and took effect January 1 of this year, requires most hospitals to make publicly available a machine-readable file of the hospital's standard charges and payer-specific prices for services, as well as more consumer-friendly, searchable information. That rule has faced stiff opposition from hospitals and others but survived legal challenges in federal court. (See the *Manatt Insights* analysis of the rule for more information.)

Under the original rule now in effect, CMS can issue penalties of up to $300 a day for noncompliance. But now, citing an observed "trend towards a high rate of hospital

noncompliance," CMS is finalizing an increase to the potential penalties and a move to a scaling-factor system. Under the scaled approach, hospitals with 30 or fewer beds still face a maximum penalty of $300 per day. But larger hospitals will see greater potential penalties. Those with between 31 and 550 beds will face a maximum penalty of $10 per bed per day out of compliance, with hospitals that have more than 550 beds seeing their liability capped at $5,500 per day. These penalties will increase with inflation in future years.

To further increase accessibility of transparency information, CMS has also clarified that hospitals must ensure that the standard charge information is easily accessible, without barriers, including but not limited to ensuring the information is accessible to automated searches and direct file downloads through a link posted on a publicly available website. This clarification now bars practices such as failing to provide a link for downloading a single machine-readable file, using "blocking codes" or CAPTCHA, and requiring the user to agree to terms and conditions or submit other information prior to access. For cases where hospitals use a price estimator tool, in lieu of meeting certain consumer-friendly display requirements, CMS has issued several clarifications, such as highlighting a requirement that the tool must generate a single dollar amount that is tailored to the individual seeking the estimate, taking the individual's circumstances into consideration when developing the estimate.

Finally, CMS is deeming certain state forensic hospitals as having met the requirements, relieving them of transparency obligations.

Changes to the Inpatient Only List

The Inpatient Only (IPO) list enumerates services that CMS considers inappropriate for outpatient services and therefore must only be performed in an inpatient setting. In last year's CY 2021 final rule, CMS began a three-year phaseout of the list by permitting Medicare to pay for nearly 300 musculoskeletal services (e.g., hip fracture fixation) for the first time when performed in an outpatient setting, with the remainder of the IPO list slated for elimination by 2024.

In this year's final rule, CMS reversed last year's decision to eliminate the IPO list. Instead, CMS codifies in regulation its long-standing criteria for determining whether a service or procedure should be removed and will use these criteria to conduct case-by-case analyses in the future.

In the proposed rule, CMS indicated that it would place the musculoskeletal procedures removed in 2021 back on the IPO list for 2022. CMS finalized this proposal, with the exception of the following CPT codes, which CMS removed from the IPO list:

- CPT code 22630 (Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar)

- CPT code 23472 (Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (for example, total shoulder)

- CPT code 27702 (Arthroplasty, ankle; with implant (total ankle) and their corresponding anesthesia codes: CPT code 00630 (Anesthesia for procedures in lumbar region; not otherwise specified), CPT code 00670 (Anesthesia for extensive spine and spinal cord procedures (e.g., spinal instrumentation or vascular procedures)

- CPT code 01638 (Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; total shoulder replacement)

- CPT 01486 (Anesthesia for open procedures on bones of lower leg, ankle, and foot; total ankle replacement)

CMS also classified CPT code 0643T (Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach) as an inpatient-only procedure.

Radiation Oncology Model

CMS finalized its proposal to launch the long-delayed Radiation Oncology (RO) Model on January 1, 2022. The RO Model was originally scheduled to go into effect on January 1, 2020, but its implementation has been continually pushed back—first to further evaluate stakeholder policy concerns related to what cancers and services are included in the RO Model, then by Congress under the Consolidated Appropriations Act, 2021 (CAA) passed in December 2020 to grant relief to impacted providers during the PHE. The RO Model is set to run from January 1, 2022, to December 31, 2026. Only congressional action could result in a further delay.

Providers located in randomly selected Core-Based Statistical Areas (CBSAs) will be required to participate; selected CBSAs have remained the same since the final rule originally published on this model in September 2020. CMS stated that selected RO Model participants have therefore had over a year to prepare for implementation.

Under the RO Model, CMS will pay participating providers a site-neutral, episode-based payment for specified professional and technical radiation therapy services furnished during a 90-day episode to Medicare fee-for-service (FFS) beneficiaries diagnosed with certain types of cancer.

The following policies were finalized:

- Removing brachytherapy from the included modalities. Originally, the model was intended to include all modalities. The previous decision to exclude intraoperative radiotherapy (IORT) and proton beam therapy remains in place.

- Removing liver cancer from the included cancer types.
- Adding an extreme and uncontrollable circumstances policy. This policy gives flexibility to reduce the administrative burden of RO Model participation, including reporting requirements, and/or to adjust the payment methodology as necessary.
- Adjusting the pricing methodology, including updating the baseline period to 2017–2019 and lowering the discounts to 3.5% for the professional component and 4.5% for the technical component.
- Finalizing that in cases where, during an episode, a beneficiary switches from traditional FFS to Medicare Advantage before treatment is complete, CMS will consider this an incomplete episode and radiotherapy services will be paid on an FFS basis rather than as part of the bundled payment.
- Modifying the current overlap policy for the Pennsylvania Rural Health Model (PARHM) to only exclude hospitals participating in PARHM, not just PARHM-eligible hospitals, and adding an overlap policy for the Community Track of the CHART Model. The RO Model would follow the same policy for overlap between the RO Model and the Medicare Shared Savings Program ACOs for the CHART ACO Transformation Track.
- In light of the current PHE and several recent natural disasters, adding an extreme and uncontrollable circumstances policy. This policy will give flexibility to reduce the administrative burden of RO Model participation, including reporting requirements, and/or to adjust the payment methodology as necessary.

CMS also includes clarifications in the final rule to help address questions from stakeholders and future RO Model participants related to the interaction between the RO Model and the Quality Payment Program.

Additional information regarding the implementation of these changes will be provided to RO Model participants by CMS via upcoming learning events and materials.

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