

CMS Issues Hospital Outpatient/ASC Final Rule, Including Modifications to Price Transparency Rule

The Centers for Medicare & Medicaid Services (CMS) yesterday released its calendar year (CY) 2022 outpatient prospective payment system (OPPS)/ambulatory surgical center (ASC) final rule that updates payment rates and makes several policy changes, generally effective on Jan 1, 2022.

Highlights of CMS' final rule follow:

Key Takeaways

In the final rule, CMS sets policies to:

- Update OPPS payment rates by 2.0% in 2022;
- Use CY 2019 claims data for CY 2022 OPPS and ASC rate setting;
- Reverse the phased elimination of the inpatient-only list (IPO) list and restore nearly all of the procedures that were removed from the list in 2021;
- Reinstate several patient safety criteria for adding a procedure to the ASC covered procedures list (CPL) and, as a result, removed almost all the procedures added to the ASC CPL in 2021;
- Continue to pay for 340B drugs at average sales price (ASP) minus 22.5%;
- Modify the hospital price transparency rule, including a significant increase to the civil monetary penalty for noncompliance;
- Remove two measures and adopt three for the Outpatient Quality Reporting Program, including a measure assessing COVID-19 vaccination rates among health care personnel.
- Require mandatory reporting of the Outpatient and ASC Consumer Assessment of Healthcare Providers and Systems patient experience survey starting in 2024; and,
- Make several modifications to the Radiation Oncology Model and officially launch the model on Jan. 1, 2022.

HIGHLIGHTS OF THE OPPS FINAL RULE

Payment Update: CMS will update OPPS rates by 2.0% for CY 2022. This change includes a market-basket update of 2.7%, as well as a productivity cut of 0.7 percentage points. These payment adjustments, in addition to other changes in the rule, are estimated to result in a net increase in OPPS payments of 1.6% compared to CY 2021 payments. For those hospitals that do not publicly report quality measure data, CMS will continue to impose the statutory 2.0 percentage point additional reduction in payment. CMS estimates that total payments to hospitals (including beneficiary costsharing) will increase by approximately \$1.3 billion in CY 2022 compared to CY 2021.

Use of CY 2019 Claims Data for CY 2022 OPPS and ASC Rate setting: Typically, CMS uses the most recently available claims data source for rate setting, which for CY 2022 rate-setting purposes would be CY 2020 claims data. However, because the CY 2020 claims data includes services furnished during the COVID-19 public health emergency (PHE), which significantly affected outpatient service utilization, the agency has determined that CY 2019 data will better approximate expected CY 2022 outpatient service utilization than CY 2020 data. As a result, as proposed, CMS will use CY 2019 data to set CY 2022 OPPS and ASC payment rates.

Partial Hospitalization Program (PHP) Update: CMS finalized its proposed methodology to calculate the community mental health center (CMHC) and hospital-based PHP geometric mean per diem costs for CY 2022. Because the geometric mean per diem costs CMS calculated for CMHC and hospital-based PHP will both decline in CY 2022 compared to CY 2021, the agency will instead use a cost floor for both types of PHP providers. That is, consistent with its established methodology, CMS will maintain the geometric mean per diem costs finalized in the prior year, CY 2021, in order to protect access to PHP services. This results in a CY 2022 PHP per diem geometric mean cost for CMHCs of \$136.14 and \$253.76 for hospital-based PHPs.

Changes to the Inpatient Only (IPO) List: CMS finalized its proposal to halt the three-year phased elimination of the IPO list that was finalized in CY 2021. Further, the agency will add back to the IPO list all the services removed in 2021, except for three arthrodesis and arthroplasty services and their corresponding anesthesia codes. In addition, CMS makes several policy modifications regarding the IPO list, including codifying the five longstanding criteria for determining whether a procedure should be removed from the IPO list.

Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A (2-Midnight Rule): For CY 2022, CMS, as proposed, will exempt from medical review for two years those procedures that were removed from the IPO list on or after Jan. 1, 2021. Specifically, they will be exempt from site-of-service claim denials, Beneficiary and Family-Centered Care Quality Improvement Organization (BFCC-QIO) referrals to recovery audit contractors (RACs) for persistent noncompliance with the 2-midnight rule, and RAC reviews for "patient status" (that is, site-of-service).

340B Drug Payment Policy, Including in Off-Campus Provider-based Departments: CMS continues its current payment policy for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B program. Specifically, the final rule stipulates that CMS will continue to pay certain 340B hospitals for drugs purchased through the 340B program at Average Sales Price (ASP) minus 22.5%. As in previous OPPS rules, CMS extends this ASP minus 22.5% payment rate to 340B-acquired drugs furnished in non-grandfathered (non-excepted) off- campus provider-based departments and applies to biosimilar drugs and other drugs without an ASP purchased through the 340B program. CMS also affirms that this 340B payment policy does *not* apply to rural sole community hospitals, children's hospitals or PPS-exempt cancer hospitals, consistent with the previous OPPS rules.

Equitable Adjustment for Devices, Drugs, and Biologicals with Expiring Pass-through Status: As a result of its use of CY 2019 claims data, rather than CY 2020 claims data, for CY 2022 rate setting, CMS will use its "equitable adjustment authority" to continue to provide separate payment, for up to four additional quarters, for 27 drugs and biologicals and one device category whose pass-through payment status will expire between Dec. 31, 2021 and Sept. 30, 2022.

Outpatient Quality Reporting Program (OQR) Provisions: For the OQR, CMS finalized nearly every provision as proposed; the only changes from the proposed rule relate to the timing of a few provisions' implementation.

Measure Removals and Additions. CMS finalized the adoption of the COVID-19 Vaccination among Health Care Personnel (HCP) measure, which was adopted in the quality reporting programs for most other clinical settings (including the inpatient quality-reporting program), beginning with the CY 2022 reporting period/CY 2024 payment determination. The measure assesses the percentage of HCP eligible to work at the hospital for at least one day during the reporting period who received a complete vaccination course against COVID-19. Facilities must collect data for at least one, self-selected week during each month and report it quarterly through the CDC National Healthcare Safety Network (NHSN) submission framework. In the final rule, CMS clarifies that facilities will report a single HCP count to NHSN by enrolled facility to include HCP eligible to work in both inpatient and outpatient settings under the same CMS Certification Number (CCN). The agency will begin publicly reporting the most recent quarter of data for this measure by CCN beginning with the October 2022 Care Compare refresh. CMS finalized the adoption of this measure for the ASC Quality Reporting Program (ASCQR) as well.

In addition, CMS will adopt the Breast Screening Recall Rates measure beginning with

the CY 2023 payment determination. The measure is a claims-based process measure, and assesses the percentage of Medicare fee-for-service beneficiaries for whom a traditional mammography or digital breast tomosynthesis (DBT) screening was performed and then followed by a diagnostic mammography, DBT, ultrasound or magnetic resonance imaging in a hospital outpatient department (HOPD) or office within 45 calendar days of the first image.

CMS will remove two measures beginning with the CY 2025 OQR program. CMS reasons that these chart-abstracted measures, Fibrinolytic Therapy Received within 30 Minutes of ED Arrival (OP-2) and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP-3) evaluate issues better addressed by a more broadly applicable electronic clinical quality measure (eCQM); accordingly, CMS will adopt a new measure in their place: ST-Segment Elevation Myocardial Infarction (STEMI) eCQM. Reporting of this new measure will be voluntary for the CY 2023 reporting period and then mandatory beginning with the CY 2024 reporting period.

Finally, CMS will require hospitals and ASCs to report the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31, ASC-11) measure beginning with the CY 2025 reporting period (a start date later than originally proposed). This measure, which uses pre- and post-operative surveys to assess the percentage of adult patients who had cataract surgery and had improvement in visual function, has been voluntarily reported since the CY 2015 reporting period.

Outpatient and ASC Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based Measures. CMS finalized its proposal to implement five OAS CAHPS survey-based measures and thus require collection of the OAS CAHPS survey. Notably, CMS will allow survey administration via a web-based module, which has yet been unavailable for CAHPS surveys. For HOPDs, collection and reporting will be voluntary during the CY 2023 reporting period, and then mandatory beginning with the CY 2024 reporting period.

CMS will allow ASCs to administer the survey and report data voluntarily beginning with the CY 2024 reporting period, with mandatory reporting beginning with the CY 2025 reporting period. The agency offers this extension "due to the impact of the ongoing PHE for COVID-19 on ASC facilities."

<u>Validation Updates</u>. CMS will reduce the time allowed for the submission of chartabstracted measure data for validation beginning with the CY 2024 payment determination from 45 calendar days to 30 calendar days. The agency also finalized its proposals to add criteria to how it selects a sample of hospitals for validation and to expand exemptions from validation in extraordinary circumstances to eCQMs.

HIGHLIGHTS OF THE MEDICARE ASC FINAL RULE

ASC Payment Update: For CYs 2019 through 2023, CMS set a policy to update the ASC payment system using the hospital market-basket update instead of the Consumer Price Index for all urban consumers. As such, for CY 2022, CMS will increase payment rates under the ASC payment system by 2.0% for ASCs that meet the ASC quality reporting requirements. This increase is based on a hospital market-basket percentage

increase of 2.7% minus a proposed productivity adjustment of 0.7 percentage point. CMS estimates that payments to ASCs will increase by \$40 million in CY 2022 compared to CY 2021.

Changes to the List of ASC-covered Surgical Procedures: CMS finalized its proposal to re-adopt the ASC Covered Procedures List (CPL) criteria that were in effect in CY 2020. It also will remove 255 of the 258 procedures that were added to the ASC CPL in CY 2021. The agency also is finalizing the adoption of a nomination process, which will begin in March 2022, to allow stakeholders to nominate surgical procedures to be added to the ASC CPL. If CMS determines that a nominated procedure meets the requirements to be added to the ASC CPL, and the agency would propose to add it beginning in CY 2023.

ASCQR Provisions: In addition to the OQR provisions that affect ASCs, the agency will also require the reporting of four previously suspended measures beginning with the CY 2023 reporting period. These measures include Patient Burn (ASC-1), Patient Fall (ASC-2), Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (ASC-3), and All-Cause Hospital Transfer/Admission (ASC-4).

OTHER ISSUES

Price Transparency: CMS finalizes, as proposed, a number of modifications to the hospital price transparency rule, including significant increases to the civil monetary penalty (CMP) for noncompliance. Currently, the CMP is set at a maximum amount of \$300/day. Beginning Jan. 1, 2022, CMS will scale up the CMP based on bed count. The maximum penalty will remain at \$300/day for small hospitals (30 or fewer beds), but will be set at \$10/bed/day for larger hospitals, with a daily cap of \$5,500. In addition, CMS finalizes prohibiting specific barriers to accessing the machine-readable files, including through automated searches and direct downloads.

CMS also provides additional clarifications on compliant price estimator tools for those hospitals that chose to use them to fulfill the shoppable service requirement.

Request for Information (RFI) on Rural Emergency Hospitals (REHs): In the proposed rule, CMS solicited public comments on the establishment of REHs. The agency stated that it received robust comments in response to the RFI and will take those comments into consideration during the rulemaking process for the development of REH requirements. Future rulemaking will include additional opportunities for public comments.

Radiation Oncology Model: At the direction of the Patient Access and Medicare Protection Act of 2015, CMS developed the Radiation Oncology (RO) Model to test whether site-neutral, modality agnostic, bundled payments for radiotherapy (RT) could reduce Medicare costs while preserving or enhancing the quality of care. The model is mandatory for physician group practices, HOPDs and freestanding radiation therapy centers that deliver RT services in randomly selected areas of the country. It was slated

to launch on Jan. 1, 2021, but was delayed six months by CMS and another six months by Congress. In this rule, CMS finalizes Jan. 1, 2022 as the official start of the RO, declining to delay it further.

CMS also finalizes several technical proposals to implement the model beginning next year, including:

- Removing liver cancer from the model;
- Removing brachytherapy from the list of included modalities in the model;
- Exempting from the model HOPDs that are participating in the Community Transformation track of the CHART Model and the Pennsylvania Rural Health Model; and
- Adopting an extreme and uncontrollable circumstances (EUC) policy.

Additionally, CMS finalizes its proposal to lower the model discount factors to 3.5% for the professional component of the payment and 4.5% for the technical component, declining to set the discounts at or below 3% in line with other CMS models. CMS also finalizes with modification its new track system related to Quality Payment Program status of RO model participants.