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Special Bulletin

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CMS Issues Hospital Outpatient/ASC Proposed 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) proposed rule.

In addition to standard updates, the rule would: reverse two policies finalized in CY 2021 related to the inpatient only (IPO) list and the ASC covered procedures list (CPL); significantly increase the civil monetary penalty for noncompliance with the hospital price transparency rule; solicit comments on establishing a new provider type called the Rural Emergency Hospital; and modify the Radiation Oncology Model.

Comments on the proposed rule are due by Sept. 17.

Key Takeaways

CMS proposes to:

- Update OPPS payment rates by 2.3% in 2022;
- Use CY 2019 claims data for CY 2022 OPPS and ASC ratesetting;
- Reverse the phased elimination of the IPO list and restore 298 procedures that were removed from the IPO list previously;
- Reinstate several patient safety criteria for adding a procedure to the ASC CPL and, as a result, remove 258 procedures from the ASC CPL;
- 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 allow survey administration via web-based module;
- Solicit public comments on the establishment of the Rural Emergency Hospital model; and,
- Make several modifications to the Radiation Oncology Model and officially launch the model on Jan. 1, 2022.

AHA Take: In a statement shared with the media yesterday, AHA said that the proposed rule includes a number of proposals that will help hospitals and health systems better provide care in their communities. We were pleased that CMS recognized the unique role that hospital outpatient departments serve in caring for patients, by proposing to roll back two problematic policies it advanced last year. The first policy would have eliminated the list of medically complex services that Medicare will only pay for when performed in the inpatient setting, and

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the second would have allowed very complicated procedures to be provided in ASCs, both of which could have negatively impacted Medicare patients' safety and quality of care.

We also welcome the request for information on the Rural Emergency Hospital model, which will help rural hospitals continue to serve as an access point to care in their communities. The pandemic has been especially challenging to rural facilities and this model will help to ensure that patients continue to have the access they need.

Further, although AHA is committed to helping patients access financial and other information patients need to make decisions about their care, we are deeply concerned about the proposed increase in penalties for non-compliance, particularly in light of substantial uncertainty in the interpretation of the rules.

Finally, we are disappointed that CMS proposes to continue to deeply cut OPPS payments to 340B hospitals, and we urge CMS to reverse this punitive policy in the final rule. These cuts directly harm 340B hospitals and their ability to care for their patients, contravening Congress' intent in establishing the 340B program. These cuts are enabled by a lower court's deference to the government's inaccurate interpretation of the law, which is the crux of the legal issue the Supreme Court will review in its upcoming term. For more than 25 years, the 340B program has helped hospitals stretch scarce federal resources to reach more patients and provide more comprehensive services. This proposal would undoubtedly result in the continued loss of resources for 340B hospitals and exacerbate the strain on these hospitals, especially as the COVID-19 pandemic continues.

Highlights of CMS' proposals important to hospitals and health systems follow.

HIGHLIGHTS OF THE OPPS PROPOSED RULE

Payment Update: CMS proposes to update OPPS rates by 2.3% for CY 2022. This change includes a market-basket update of 2.5%, as well as a productivity cut of 0.2 percentage points. **These payment adjustments, in addition to other proposed changes in the rule, are estimated to result in a net increase in OPPS payments of 2.3% compared to CY 2021 payments.** For those hospitals that do not publicly report quality measure data, CMS would continue to impose the statutory 2.0 percentage point additional reduction in payment. CMS estimates that total payments to hospitals (including beneficiary cost-sharing) would 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 Ratesetting: 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 would better approximate expected CY 2022

outpatient service utilization than CY 2020 data. As a result, CMS proposes to use CY 2019 data to set CY 2022 OPPS and ASC payment rates.

Partial Hospitalization Program (PHP) Update: CMS proposes to follow its existing 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 would both decline in CY 2022 compared to CY 2021, the agency proposes to instead use a cost floor for both types of PHP providers. That is, consistent with its established methodology, CMS proposes to 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 proposed 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: As urged by the AHA, CMS proposes to halt the three-year phased elimination of the IPO list that was finalized in CY 2021. Further, the agency conducted a clinical review of the services removed from the IPO list in CY 2021. As a result, it also proposes to add the 298 services removed from the IPO list in CY 2021 back to the IPO list beginning in CY 2022. In addition, CMS requests comments on several policy modifications regarding the IPO list.

Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A (2-Midnight Rule): For CY 2022, CMS proposes to exempt from medical review for two years those procedures that were removed from the IPO list on or after Jan. 1, 2021. Specifically, they would 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 proposes to continue 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 agency proposes to 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 proposes to extend 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 again proposes 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 proposal to use CY 2019 claims data, rather than CY 2020 claims data, for CY 2022 ratesetting, CMS proposes to 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) Proposals: CMS proposes several changes to the OQR that would take effect over the next few years.

Measure Removals and Additions. CMS proposes to adopt the COVID-19 Vaccination among Health Care Personnel (HCP) measure, which has been proposed for adoption in the quality reporting programs for most other clinical settings (including the inpatient quality reporting program, or IQR), beginning with the CY 2022 reporting period/CY 2024 payment determination. The measure assesses the estimated 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. According to the measure's specifications, acute care facilities would count HCP working in all inpatient or outpatient units that are physically attached to the inpatient acute care facility site and share the same CCN, as well as HCP working in departments that are affiliated with but physically separate from the acute care facility as long as they share the same CCN. Data would be collected for at least one, self-selected week during each month and reported quarterly through the Centers for Disease Control and Prevention National Healthcare Safety Network (NHSN) submission framework. CMS proposes the adoption of this measure for the ASC Quality Reporting Program (ASCQR) as well.

In addition, CMS proposes to 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 an outpatient or office within 45 calendar days of the first image.

CMS also proposes to 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), concern issues better addressed by a more broadly applicable electronic clinical quality measure (eCQM); accordingly, CMS proposes to adopt a new measure in their place: ST-Segment Elevation Myocardial Infarction (STEMI) eCQM.

The STEMI eCQM is a process measure that assesses the percentage of adult ED patients with a diagnosis of STEMI who received fibrinolytic therapy within 30 minutes, received percutaneous coronary intervention (PCI) within 90 minutes of arrival, or who were transferred to a PCI-capable hospital within 45 minutes of ED arrival at a non-PCI-capable hospital. The measure would be reported voluntarily beginning with the CY 2023 reporting period, and then mandatorily beginning with the CY 2024 reporting period.

Finally, CMS proposes to require hospitals to report the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) measure beginning with the CY 2023 reporting period. 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 previously adopted five measures based on the OAS CAHPS survey. However, the agency delayed implementation of these measures due to several operational concerns. The OAS CAHPS survey has been collected on a voluntary basis since 2016. In this rule, CMS proposes to implement the five survey-based measures and thus require collection of the OAS CAHPS survey. Collection and reporting would be voluntary during the CY 2023 reporting period, and then mandatory beginning with the CY 2024 reporting period. Notably, CMS proposes to allow survey administration via a web-based module, which has as yet been unavailable for CAHPS surveys. These provisions would affect ASCs as well as hospital outpatient departments (HOPDs).

Validation Updates. CMS proposes to adjust the time period for chart-abstracted measure data validation beginning with the CY 2024 payment determination from 45 calendar days to 30 calendar days. The agency also proposes to add criteria to how it selects a sample of hospitals for validation, and to expand exemptions from validation in extraordinary circumstances to eCQMs.

Requests for Information. CMS requests feedback on several topics affecting the OQR and ASCQR, including:

- The potential future adoption of a hospital-level patient-reported outcome measure assessing improvement in pain and functioning following elective total hip/total knee arthroplasty surgery;
- Stratifying performance results on several OQR measures by dual eligibility for Medicare and Medicaid as well as race and ethnicity;
- Collecting a minimum set of demographic data using standardized and interoperable electronic health record standards;
- The future of digital quality measurement; and
- The future development of a measure assessing pain management surgical procedures performed in ASCs.

HIGHLIGHTS OF THE MEDICARE ASC PROPOSED 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 proposes to increase payment rates under the ASC payment system by 2.3% for ASCs that meet the ASC quality reporting requirements. This proposed increase is based on a proposed hospital market-basket percentage increase of 2.5% minus a proposed productivity adjustment of 0.2 percentage point. CMS estimates that payments to ASCs would increase by $90 million in CY 2022 compared to CY 2021.

Proposed Changes to the List of ASC-covered Surgical Procedures: As urged by the AHA, CMS proposes to re-adopt the ASC Covered Procedures List (CPL) criteria that were in effect in CY 2020. It also would remove 258 of the 267 procedures that were

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added to the ASC CPL in CY 2021. CMS requests comments on whether any of the 258 procedures meet the CY 2020 criteria that it proposes to reinstate. The agency also proposes to change the notification process adopted in CY 2021 to a nomination process, under which stakeholders could nominate procedures they believe meet the requirements to be added to the ASC CPL. The formal nomination process would begin in CY 2023.

ASCQR Proposals: In addition to the OQR proposals that affect ASCs, the agency also would require the reporting of four previously suspended measures and one previously voluntary measure 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), All-Cause Hospital Transfer/Admission (ASC-4), and Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (ASC-11).

OTHER ISSUES

Price Transparency: CMS proposes 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. CMS proposes to scale up the CMP based on bed count, with a minimum of $300/day for small hospitals (30 or fewer beds) and an additional $10/bed/day for larger hospital with a daily cap of $5,500. CMS seeks comment on this approach, as well as alternative calculations for scaling the CMPs, such as hospital revenue, the nature, scope, severity, and/or duration of noncompliance, and the reason for noncompliance.

In addition, CMS proposes to prohibit specific barriers to accessing the machine-readable files, including through automated searches and direct downloads. CMS also proposes to clarify the expected output of price estimator tools for those hospitals that chose to use them to fulfill the shoppable service requirement. CMS specifies that the tools need to provide a cost estimate for the amount expected to be paid by the patient that takes into consideration the individual's insurance information. Finally, CMS seeks comment on a number of issues that it may consider for future rulemaking, including best practices for online cost estimator tools, methods for identifying and highlighting exemplar hospitals, and opportunities to improve the standardization of the machine-readable files.

Request for Information on Rural Emergency Hospitals: CMS solicits public comments on the establishment of a Rural Emergency Hospital (REH) model, a new Medicare provider type established by the Consolidated Appropriations Act, 2021. Critical access hospitals and small rural hospitals that convert to REHs may furnish REH services for Medicare payment beginning in 2023 (see our Special Bulletin for more information on REHs). Among other inputs, CMS requests stakeholder feedback on health and safety standards that should apply to REHs for them to be certified to participate in the Medicare program, as well as broad input on conditions of participation. Additionally, CMS asks for public comments on health equity focused issues, payment policies, and the establishment of quality measure requirements for REHs.

Radiation Oncology Model: At the direction of the Patient Access and Medicare Protection Act of 2015, CMS developed a 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 proposes to officially start the RO model on Jan. 1, 2022, declining to delay it further. This proposal rejects the urging of the AHA and many others to postpone the model launch in light of the ongoing COVID-19 pandemic and the lack of available information on the model.**

CMS also makes 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; lowering the model discounts to 3.5% for the professional component of the payment and 4.5% for the technical component; and adopting an extreme and uncontrollable circumstances policy.

Comment Solicitation on Temporary Policies for the PHE for COVID-19: In response to the COVID-19 pandemic, CMS undertook emergency rulemaking to implement a number of flexibilities to address the pandemic. While many of these flexibilities will expire at the conclusion of the PHE, CMS requests comment on whether there are certain policies that should be made permanent. Specifically, the agency is seeking comment on: mental health and other services furnished by hospital staff to beneficiaries in their homes through use of communication technology; providers furnishing services in which the direct supervision for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services requirement was met by the supervising practitioner being available through audio/video real-time communications technology; and the need for specific coding and payment to remain available under the OPPS for specimen collection for COVID-19.

NEXT STEPS

CMS will accept comments on the rule through Sept. 17, and a final rule is expected around Nov. 1. The policies and payment rates will generally take effect Jan. 1, 2022. Watch for a more detailed analysis of the proposed rule in the coming weeks, as well as an invitation to an AHA members-only call to discuss the proposed rule.

If you have further questions, contact Roslyne Schulman, AHA director of policy, at rschulman@aha.org.