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ALERT ▪ Health Care

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CMS Publishes Calendar Year 2023 Hospital Outpatient Payment Proposed Rule and Addresses 340B Drug Payments, Organ Acquisition Costs, Pandemic Related Payment Changes, Rural Hospitals

Attorneys
Stephanie A. Webster
James Harold (Harry) Richards
Alex J. Talley
Joshua Balk

On July 26, 2022, the Centers for Medicare & Medicaid Services ("CMS") published in the Federal Register its annual proposed rule for the calendar year ("CY") 2023 outpatient prospective ("OPPS") and ambulatory surgical center ("ASC") payment systems. This Alert details key changes proposed by CMS on the following topics: A. Payment for 340B Drugs; B. Reimbursement for Organ Acquisition Costs; C. Changes Relating to COVID-19 Pandemic, including Updates to the Conversion Factor, Claims Data Used for Ratesetting, a Payment Adjustment for the Purchase of Approved Surgical N95 Respirators, and Mental Health Telehealth Services; D. Use of Information Related to Hospital Transactions; and E. Policies for a New Category of Rural Hospitals.

Comments on these proposals are due to CMS by September 13, 2022. We recommend you consider submitting comments on any provision potentially affecting your organization. Please feel free to reach out to your Ropes & Gray advisor with any questions about these proposals.

A. Payment for 340B Drugs

1. CMS addresses its payment methodology for drugs acquired through the 340B program in light of the Supreme Court's June 15, 2022 decision in *American Hospital Association v. Becerra*, in which the Court struck down a CMS rule providing payment for average sales price ("ASP") minus 22.5 percent as a violation of the Medicare Act. Our prior alert evaluating this decision can be located here. CMS claims that because it had already finalized the proposed rule prior to the Court's decision and did not have time to change the payment rates, it is formally proposing to continue to pay 340B hospitals at a rate of ASP minus 22.5 percent for CY 2023, but states that the agency fully anticipates reverting to an ASP plus 6 percent policy for all hospitals in the final rule. CMS also states that it intends to make this change in reimbursement to 340B hospitals budget neutral by decreasing the conversion factor to account for the increased reimbursement to 340B hospitals. In its accompanying data files, CMS estimates that this change would result in a $1.96 billion decrease in the total conversion factor amount for CY 2023. For the prior CYs 2018 through 2022 impacted by this policy, the agency notes the Court did not rule on any specific remedy and therefore does not make any specific proposals. Instead the agency requests public comments on the best way to craft potential remedies.

B. Reimbursement for Organ Acquisition Costs

2. CMS proposes to revise the methodology of counting organs for Medicare's share of reimbursement for organ acquisition costs, the methodology under which each organ procurement organization's kidney standard acquisition charge is determined, and the process for reconciliation and settlement of organ acquisition costs. In the FY 2022 IPPS proposed rule, CMS proposed to begin requiring organizations to track transplanted organs and determine if the recipients were Medicare beneficiaries in order to calculate Medicare's share of the total amount of transplanted organs. CMS did not finalize this earlier proposal. In the CY 2023 OPPS proposed rule, CMS states that in response to comments submitted to its earlier proposal, it now proposes that transplanting hospitals and organ procurement organizations would report only organs actually transplanted into Medicare beneficiaries in the transplanting hospital for purposes of calculating Medicare's share of organ acquisition costs. Organs that the transplant hospital furnishes to other hospitals or organ procurement organizations would be removed entirely from the Medicare share fraction, removing any need for the

organization to track the recipients. CMS asks for comments with detailed information from transplanting hospitals, organ procurement organizations, and other interested parties on how this proposed policy would impact their organizations. Additionally, in order to ensure that independent organ procurement organizations' kidney standard acquisition charges appropriately cover their costs, CMS is considering a methodology under which the organizations—rather than the Medicare contractor—would establish their kidney standard charges, similar to how they establish their standard charges for non-renal organs. Under this methodology, an organization would estimate the reasonable and necessary costs it expects to incur for procuring deceased donor kidneys and divide that estimated amount by the projected number of deceased donor kidneys the organization expects to procure within its cost reporting period. Finally, CMS proposes to amend the cost report reconciliation process by requiring Medicare-certified independent organ procurement organizations to submit Medicare cost reports to the Medicare Administrative Contractor for review, reconciliation, and settlement of non-renal organ acquisition costs to determine Medicare's reasonable costs. This would mirror CMS's current approach for determining Medicare's reimbursement of organizations' kidney acquisition costs.

C. Changes Relating to Covid-19 Pandemic

3. **Conversion Factor Update**. For CY 2023, CMS is proposing an overall increase factor of 2.7 percent to the OPPS conversion factor. This 2.7 percent increase is the result of a 3.1 increase to the market basket percentage, which is based on the most recent estimate of the inpatient market basket calculation, offset by a 0.4 percent decrease to the multifactor productivity adjustment. Recently, a bipartisan collection of senators and members of the House of Representatives submitted letters to the CMS Administrator requesting that the agency update the FY 2023 inpatient market basket projection to account for historical inflation and the continuing impact of COVID-19 on hospitals. *See* 42 U.S.C. § 1395*l*(t)(3)(C)(iv). Because the OPPS conversion factor update is based in part on the inpatient market basket update, any change CMS makes in response to this Congressional outreach could be reflected in the conversion factor in the final rule.

4. **Use of Claims Data for CY 2023 OPPS and ASC Payment System Ratesetting**. CMS proposes to use CY 2021 claims data, which in most cases includes cost report data from periods beginning in CY 2018, to set payment system rates for CY 2023. For the ratesetting process, the Medicare Act requires CMS to use the best available data so that the payment rates accurately reflect estimates of the costs associated with furnishing outpatient services. Consistent with standard practice, CMS proposes to use CY 2021 claims data. But instead of using cost report data from CY 2020, as it would in the ordinary course, CMS proposes to use cost report data from CY 2018 because CMS does not believe that the CY 2020 data is the best approximation of excepted outpatient hospital services due to the impacts of the COVID-19 pandemic on outpatient services. Therefore, CMS says that to mitigate the impact of the COVID-19 pandemic on recent cost report data, CMS proposes to use cost report data from the June 2020 Healthcare Cost Report Information System update, which contains data only from periods prior to the COVID-19 pandemic, which is the same extract used for ratesetting for CY 2022.

5. **Payment Adjustments under the IPPS and OPPS for Approved Surgical N95 Respirators**. CMS proposes to provide payment adjustments to hospitals under both the IPPS and OPPS for the additional costs they incur to acquire domestically made surgical N95 respirators for cost reporting periods beginning on or after January 1, 2023. Payments would be provided biweekly as interim lump sum payments to the hospital and would be reconciled at cost report settlement. CMS states that it believes the adjustment reflects, and offsets, the additional marginal costs that hospitals face in procuring respirators that are made domestically, which the agency believes will help maintain the level of production of respirators made in the United States in order to be prepared for COVID-19 and future pandemics. CMS also proposes to make a downward adjustment of the OPPS of 0.01% to make the policy change budget neutral. But CMS does not propose to make the separate IPPS payment adjustment related to the costs of acquiring domestic respirators budget neutral, explaining with respect to the IPPS approach that it seeks "[t]o further support the strategic policy goal of sustaining a level of supply resilience for NIOSH-approved surgical N95 respirators that is critical to protect the health and safety of personnel and patients in a public health emergency."

6. **Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes**. CMS proposes to designate certain services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder as covered outpatient department services ("OPD") when furnished remotely by clinical staff of a hospital to Medicare beneficiaries in their homes. Currently, these telehealth services are permitted under temporary waivers granted in response to COVID-19, and this proposal would make the exception to in-person attendance permanent for these services. Under this proposal, CMS would create OPPS and ASC payment codes for these services. CMS states that it believes that when beneficiaries are in their homes and not physically within the hospital, the costs accrued by the hospital would be lower than those associated with in-person services. Accordingly, CMS proposes that payments under these new codes would be based on rates for the same services offered through the Physician Fee Schedule. Under the proposal, hospital clinical staff would be required to be physically located in the hospital, but CMS seeks comment on whether this requirement would be overly burdensome or disruptive. Additionally, the proposal would require beneficiaries to receive an in-person service within 6 months prior to receiving mental health services remotely for the first time. Beneficiaries would also generally be required to receive an in-person service within 12 months of each remote visit, subject to limited exceptions such as when an in-person visit would risk the patient's health, create undue hardship on the patient or their family, or would result in terminating care that has been beneficial. CMS proposes to require that hospital clinical staff must have the capability to furnish two-way, audio/video services but may use audio-only communications technology in the event of an individual patient's technological limitations, abilities, or preferences.

D. Request for Information Related to Hospital Transactions

7. Earlier this year, CMS released data on hospital and skilled nursing facility mergers, acquisitions, consolidations, and changes of ownership going back to 2016. CMS is now seeking comment on how this already gathered data could be used to promote competition across the health care system or protect the public from what it characterizes as harmful effects of health care consolidations. CMS released this data in response to Executive Order (14036) on Promoting Competition in the American Economy, which developed a whole-of-government effort to promote competition in the American economy and specifically identified hospital consolidation as an area of concern. CMS's stated intent of the data release was to increase public transparency and to foster research to better understand the effects of these health care transitions on health care affordability in their communities. CMS seeks comment on what additional data already collected should be released and on whether there are additional provider types for which this information should be released.

E. Policies for Rural Hospitals

8. **Standards for New Category of "Rural Emergency Hospitals"**. CMS proposes standards for rural emergency hospitals (REHs), a new Medicare provider type established by Section 125 of the Consolidated Appropriations Act of 2021. Hospitals may convert to REHs if they were critical access hospitals or rural hospitals with not more than 50 beds participating in Medicare as of December 27, 2020. In a separate rulemaking, CMS proposes defining REHs as entities that furnish emergency department and observation care, along with other outpatient medical and health services specified by the Secretary, that do not exceed an annual per patient average of 24 hours. *See* 87 Fed. Reg. 40,350, 40,388 (July 6, 2022). In the separate OPPS rulemaking, CMS proposes the following standards relating to payment, quality measures, and enrollment for these providers:

- Treating all services that would otherwise be paid under the OPPS as REH services, with REH services paid at an amount equal to the OPPS payment rate for the covered outpatient department service plus 5 percent.

- Permitting REHs to provide additional outpatient services that are not otherwise paid under the OPPS, such as services paid under the Clinical Lab Fee Schedule, with such services paid under the applicable fee schedule without the additional 5 percent payment.

- Providing a monthly facility payment calculated pursuant to a detailed formula set forth in the proposal that would increase in subsequent years based on the hospital market basket percentage increase.

- Implementing a statutory provision that precludes administrative and judicial review of the determination of whether a facility meets the REH requirements and the determination of the REH payment amounts.

- Requiring general compliance with CMS's enrollment procedures, although CMS proposes that hospitals wishing to convert to REHs would not need to submit initial enrollment applications, but could submit the much shorter Form CMS-855A change of information (with no application fee), which CMS believes would expedite the process of converting to an REH.

- Revising the physician self-referral law to incorporate the new REH provider type, including a new exception for ownership or investment interests in REHs and revisions to certain existing exceptions to ensure they are applicable to compensation arrangements involving REHs.

9. **Payment to Rural Sole Community Hospitals (SCHs) at Full OPPS Payment Rate for Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments**. CMS proposes to exempt excepted off-campus provider-based outpatient departments of rural SCHs from the payment cuts initially adopted by CMS in the CY 2019 final rule. Pursuant to that earlier rule, under its so-called "volume control" method, CMS currently pays the equivalent of the Physician Fee Schedule payment rate for clinic visits provided at an excepted off-campus provider-based department, an amount that is approximately 60 percent less than the OPPS payment rate. CMS claims that it adopted this method in CY 2019 to control unnecessary increases in the volume of clinic visit services in provider-based departments by providers seeking to maximize payment. CMS proposes to exempt excepted off-campus provider-based departments of rural SCHs from this payment policy, recognizing that these hospitals are often the only source of care in their communities. Accordingly, beginning with CY 2023, CMS proposes to pay clinic visit services furnished at an off-campus provider-based department of a rural SCH at the full OPPS rate for the clinic visit service. Additionally, CMS seeks comments on whether it would be appropriate to exempt other rural hospitals, such as those with under 100 beds, from the Physician Fee Schedule payment rate for clinic visit services.