ROPES & GRAY

ALERT

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

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On November 1, 2022, the Centers for Medicare & Medicaid Services ("CMS") published the final rule for the calendar year ("CY") 2023 outpatient prospective payment system ("OPPS") and the ambulatory surgical center ("ASC") payment system. In August 2022, following publication of the proposed rule, we circulated an Alert summarizing key aspects of CMS's proposals. Below is a short summary of what CMS determined regarding each of the following topics in the final rule: 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. In short, CMS finalized a majority of its proposals in this final rule. Notably, however, CMS (1) took no action regarding the use of hospital transaction data to promote competition, (2) increased the OPPS conversion factor from $84.177 to $85.585, reflecting the effect of a 3.8-percent increase factor offset by various budget neutrality adjustments, and (3) did not respond to comments submitted in response to the agency's "request for information" related to reimbursement for organ acquisition costs, stating that it would use those comments to "inform future policy development." Please feel free to reach out if you have any questions about any of these issues.

A. Payment for 340B Drugs

1. Following 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 of average sales price ("ASP") minus 22.5 percent for drugs purchased through the 340B program as a violation of the Medicare Act, CMS has reverted to paying 340B hospitals at ASP plus 6 percent for 2023. CMS stated that it will continue to require that the 340B modifiers (JG and TB) be used on claims submissions for CY 2023 to allow the agency to track the utilization of 340B-purchased drugs and biologicals under the OPPS, but indicated that the modifiers will have no effect on payment rates. CMS made this change in reimbursement to 340B hospitals budget-neutral by decreasing the OPPS conversion factor (the standard rate for outpatient payments adjusted on an annual basis) by 3.09 percent to account for the increased reimbursement to 340B hospitals. While CMS stated that many commenters objected to the agency's offset, CMS claimed that under the terms of the OPPS statute, it is required to make a corresponding budget neutrality adjustment to account for the increase in reimbursement to 340B hospitals. In the proposed rule, the agency had requested comments on options to craft potential "remedies" for the prior CYs 2018 through 2022 in light of the litigation but did not finalize any changes for these earlier years in the rule. The agency stated that the majority of comments requested that the agency pay hospitals the additional amounts owed for 340B drug payments made between 2018 and 2022 and that the agency should not seek to recoup any funds to offset those payments. The agency said it plans to issue a separate proposed rule addressing the proposed remedy for 340B drug claims paid during 2018 through 2022 in advance of the release of the CY 2024 OPPS proposed rule, which is expected in summer 2023. The agency's payment for 340B purchased drugs for the 2018–2022 years is also currently the subject of continuing litigation in the *American Hospital Association* case back in the District Court for the District of Columbia.

B. Reimbursement for Organ Acquisition Costs

2. In the final rule, CMS did not respond to comments that it received in response to the proposed rule's "request for information" regarding organ acquisition costs. In particular, in the proposed rule, CMS requested information on: (1) a new methodology for counting organs under which 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; (2) a revised methodology under which organ procurement organizations—rather than Medicare contractors—would establish their kidney standard charges; and (3) potentially amending the cost report reconciliation process to require Medicare-certified independent organ procurement organizations to submit Medicare cost reports to the Medicare contractors for review, reconciliation, and settlement of non-renal organ acquisition costs to determine Medicare's reasonable costs. In the final rule, CMS stated that it was "not responding to specific comments submitted" in response to the proposed rule and that the agency "intend[ed] to use this input to inform future policy development."

C. Changes Relating to COVID-19 Pandemic

3. **Conversion Factor Update**. For CY 2023, CMS finalized an overall increase factor of 3.8 percent to the OPPS conversion factor (separate from the 3.09-percent decrease to the conversion factor to account for 340B payments discussed above) instead of the proposed 2.7 percent. As proposed, the 2.7-percent increase was the result of a 3.1-percent increase to the market basket percentage, which was based on the most recent estimate of the inpatient market basket calculation at the time, offset by a 0.4-percent decrease to the multifactor productivity adjustment. But based on more recent data that the agency had proposed to use if they became available, CMS finalized a 4.1-percent increase to the market basket percentage, offset by a 0.3-percent productivity adjustment to arrive at 3.8 percent.

4. **Use of Claims Data for CY 2023 OPPS and ASC Payment System Ratesetting.** CMS finalized without modification its proposal 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. Instead of using cost report data from CY 2020 as it would in the ordinary course, CMS said it finalized its proposal to use cost report data from CY 2018 because CMS did not believe that the CY 2020 data are the best approximation of excepted outpatient hospital services due to the impacts of the COVID-19 pandemic on outpatient services. Therefore, in order to mitigate the impact of the COVID-19 pandemic on recent cost report data, CMS's final rule used cost report data from the June 2020 Healthcare Cost Report Information System update. That update contains cost report data only from periods prior to the COVID-19 pandemic and is the same extract used for ratesetting for CY 2022.

5. **Payment Adjustments under the IPPS and OPPS for Approved Surgical N95 Respirators.** CMS finalized without modification its proposal to provide payment adjustments to hospitals under both the inpatient and outpatient prospective payment systems for the additional costs they incur to acquire domestically-made surgical N95 respirators for cost reporting periods beginning on or after January 1, 2023. Under the final rule, payments would be provided biweekly as interim, lump-sum payments to hospitals and would be reconciled at cost report settlement to offset the additional marginal costs that hospitals face in procuring respirators that are made domestically. The agency believed that this approach would help maintain the level of production of respirators made in the United States to be prepared for COVID-19 and future pandemics. CMS also finalized a downward 0.01-percent adjustment to the OPPS conversion factor to make the policy change budget-neutral.

6. **Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes.** CMS finalized its proposal 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 hospital clinical staff to Medicare beneficiaries in their homes. Before this final rule, these telehealth services were permitted under temporary emergency COVID-19 waivers. The final rule made the exception to in-person attendance for these services permanent. CMS finalized HCPCS payment codes for these services based on the payment rates for comparable CPT codes under the Physician Fee Schedule. In contrast to the proposed rule, the final rule provided that hospital clinical staff need not be

physically located in hospitals to provide mental health services to beneficiaries in their homes. CMS said it made this change to "maximize flexibility, particularly in areas where there is a shortage of healthcare practitioners." CMS finalized the proposals requiring that beneficiaries receive in-person services within six months prior to receiving mental health services remotely for the first time and that beneficiaries receive in-person services within 12 months of remote visits (with limited exceptions such as when in-person visits would risk the patients' health, create undue hardship on the patients or their families, or would result in terminating care that had been beneficial). CMS clarified, however, that the requirement for in-person visits within six months of the initial telehealth mental health services would take effect beginning after the 152nd day following the end of the public health emergency. Finally, CMS finalized its proposal to require that hospital clinical staff have the capability to furnish two-way, audio/video services but specified that they may use audio-only communications technology in the event of patients' technological limitations, abilities, or preferences.

D. Request for Information Related to Hospital Transactions

7. CMS did not make any proposals in response to comments it requested on how data it previously released on hospital and skilled nursing facility mergers, acquisitions, consolidations, and changes of ownership could be used to promote competition across the healthcare system or protect the public from what it characterized as harmful effects of healthcare consolidations. CMS released the data earlier this year 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 healthcare transitions on healthcare affordability in their communities. Many of the comments CMS received advocated for transparency in hospital pricing generally, while others noted that other agencies like the Department of Justice and Federal Trade Commission can already study the healthcare industry and release reports. CMS stated they would take the public comments into consideration in the future. For more information on this topic, we invite you to listen to a recently released podcast entitled "Medicare Rules: Promoting Competition?"

E. Policies for Rural Hospitals

8. **Standards for New Category of "Rural Emergency Hospitals."** CMS finalized 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. CMS finalized its proposal to define REHs, after receiving no comments, 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 annual per patient averages of 24 hours. CMS also finalized, largely as proposed, the following standards relating to payment, quality measures, and enrollment for these providers:

- Defining REH services to include all services that are paid under the OPPS when furnished in OPPS hospitals, with the exception of acute inpatient services.
- Treating all services that would otherwise be paid under the OPPS as REH services, with REH services paid at amounts equal to the OPPS payment rates for the covered outpatient department services 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 monthly facility payments calculated according to a detailed formula 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 determinations of whether facilities meet the REH requirements and of the REH payment amounts.

- Requiring general compliance with CMS's enrollment procedures. CMS finalized its proposal that hospitals wishing to convert to REH status need not submit initial enrollment applications and could instead submit the much shorter Form CMS-855 "A change of information" (with no application fee). CMS believed that this approach would expedite the process of converting to REH status.

- Revising the physician self-referral law to incorporate the new REH provider type, including revisions to certain existing exceptions to ensure they are applicable to compensation arrangements involving REHs. However, CMS did not finalize its proposed new exception for ownership or investment in REHs, finding that it "may present a risk of patient or program abuse."

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 finalized its proposal 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. Under that 2019 rule, CMS paid the equivalent of the Physician Fee Schedule payment rate for clinic visits provided at excepted off-campus provider-based departments, an amount that is approximately 60 percent less than the OPPS payment rate. CMS claimed 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 finalized its proposal to exempt excepted off-campus provider-based departments of rural SCHs from this payment policy, concluding that this approach would help to maintain access to care in rural areas by ensuring rural providers are paid for clinic visit services provided at off-campus provider-based departments at the same rate paid when the services are furnished in on-campus departments. CMS also noted that the new policy aligns with other special adjustments that SCHs receive, including a 7.1-percent payment adjustment for services and procedures paid under the OPPS. Under the final rule, beginning in CY 2023, CMS will pay for clinic visit services furnished at off-campus provider-based departments of rural SCHs at the full OPPS rate for the clinic visit services. CMS did not finalize a similar exception for other provider types, noting that it believed that "the underlying principles of the clinic visit policy continue to justify application" of the existing payment methodology for clinic visits to other hospital types, "including most rural and safety-net providers," and that these other provider types do not "demonstrate the additional resource costs that rural SCHs do."