

LEGAL UPDATES

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Services

340B Drug Pricing
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CMS Releases CY 2023 OPPS and ASC Proposed Rule

The Centers for Medicare and Medicaid Services (CMS) issued the calendar year (CY) 2023 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Proposed Rule on July 15, 2022. The Proposed Rule addresses many pressing issues in healthcare, such as transparency, competition, 340B drug pricing, rural health and behavioral health. The Proposed Rule is open for a 60-day comment period that will close on September 13, 2022.

Highlights from the Proposed Rule

Reimbursement increases

Increase of OPPS rates by 2.7%. CMS proposes to increase OPPS payment rates by a net of 2.7%. With the inflation rate nearing 10%, the meager rate increase may pose additional challenges for providers in the face of supply chain issues, labor shortages and overall recovery efforts stemming in part from the COVID-19 pandemic.

Increase in 340B reimbursement rates in response to recent

Supreme Court decision. While the Proposed Rule technically proposes to keep 340B reimbursement rates at average sales price (ASP) minus 22.5%, CMS states that it fully intends to increase 340B reimbursement rates to ASP plus 6% in its forthcoming Final Rule. This eventual rate increase comes in response to the recent Supreme Court decision, which ruled the CY 2018/2019 340B reimbursement cuts were unlawful. However, to counteract the increase, CMS proposes a decrease in the OPPS conversion factor to maintain budget

neutrality across all services. CMS is specifically seeking comments regarding how to rectify the historic underpayments.

Rural Emergency Hospitals

Expansion of services and updated payment model for Rural Emergency Hospitals. The Consolidated Appropriations Act of 2021 established Rural Emergency Hospitals (REH) as a new Medicare provider type, effective January 1, 2023, to increase comprehensive care for rural communities. In the Proposed Rule, CMS suggests considering all covered outpatient services performed at an REH as “REH services,” which would be reimbursed at a higher REH rate. Further, CMS proposes that REH service payments be calculated by adding 5% to the OPSS payment for the equivalent outpatient service. The additional 5% would not be subject to a copayment. REHs would also receive a monthly facility payment. This would be a potential benefit for many rural providers and should be supported by comments to CMS.

Simplification of provider enrollment process for REHs. CMS proposes that in order to convert from a Critical Access Hospital (CAH) to an REH, the CAH need only submit a Form 855A change of information application, rather than a full initial enrollment application, which would include a waiver of the initial application fee.

Updates to Stark Law exceptions for REHs. CMS proposes to add a new exception to the Stark Law for REHs, which would carve out ownership or investment interests in an REH. CMS also proposes updating existing exceptions so they apply to compensation arrangements where an REH is a party.

Remote behavioral health

Continued flexibilities to provide behavioral health services in the home after the public health emergency ends. Currently, patients can receive remote behavioral health services from hospital outpatient department clinical staff because of certain emergency waivers resulting from the public health emergency. CMS proposes to consider these remote behavioral health services as covered outpatient services, paid under the OPSS, even after the public health emergency expires. In order to qualify, patients would need to receive an in-person service six months or less before the first remote visit and every 12 months after the remote visit. CMS also proposes to permit providing these services via audio-only technology in order to improve health equity.

Inpatient only and ASC Covered Procedures Lists

Removal of 10 services from the inpatient only (IPO) list. In the CY 2021 OPPS Final Rule, CMS finalized its policy to eliminate the IPO list over three years. The policy was halted after a clinical review of the services removed in the first phase and many services were returned to the list. Now, CMS proposes to remove 10 services from the IPO list after noting that those 10 services meet the criteria for removal.

Addition of a procedure to ASC Covered Procedures List. CMS proposes to add a lymph node biopsy or excision to the ASC Covered Procedures List.

Transparency and competition

Promotion of competition and transparency among hospitals and skilled nursing facilities (SNF). On July 9, 2021, President Biden issued an Executive Order that referenced hospital consolidation and the negative effects it has had on certain markets, especially in rural communities. Data suggests that consolidation can increase prices without a corresponding increase in quality. This year, after reviewing Medicare Provider Enrollment, Chain, and Ownership System (PECOS) data, CMS released information to the public on hospital and SNF mergers, acquisitions, consolidations and changes in ownership to promote transparency and competition among providers. In addition, the Department of Health and Human Services (HHS) released a report, noting how changes in ownership vary based on state and the type of facility. CMS requests comments from the public on how to best use and release data to promote competition, increase transparency and protect communities from the potentially harmful effects of consolidation.

What this means to you

Rural hospital providers can now better assess whether to convert to a Rural Emergency Hospital and the impact it could have on their community, and hospitals can expect continued flexibility for behavioral health services delivered at home even after the public health emergency ends. 340B Covered Entities are strongly urged to submit comments on how CMS should rectify the unlawful 340B reimbursement cuts from calendar years 2018 through 2022. Providers should also consider submitting comments on whether to narrow the definition of REH services, and to provide suggestions on data CMS should release to effectively promote competition and transparency among healthcare providers. Our attorneys at Husch Blackwell are experienced in these analyses, drafting and submitting public comments, and handling reimbursement appeals.

Contact us

For assistance with submitting public comments, converting to a Rural Emergency Hospital, questions related to the 340B Drug Pricing Program, or other questions or assistance regarding the Proposed Rule, contact Daniel Avants, Amanda Bogle or your Husch Blackwell attorney.