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CMS Proposes Plan to Repay 340B Hospitals for Drug Underpayments and Recoup Increased Payments for Non-Drug Items and Services

On Friday (July 7), the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule detailing the agency's plan for repaying about 1,600 340B hospitals $9 billion in cuts to hospital outpatient payments under the 340B Drug Discount Program after the Supreme Court ruled the cuts unlawful. CMS' proposed rule includes a hospital-by-hospital breakdown of expected repayment amounts in Addendum AAA (linked below). The proposed rule also details the agency's plan to recoup increased payments for non-drug items and services over a 16-year period.

CMS is accepting comments on the proposed rule until September 5. CMS anticipates issuing the final rule before the Calendar Year (CY) 2024 Outpatient Prospective Payment System/Ambulatory Surgery Center (OPPS/ASC) final rule is published in Fall 2023. The proposed CY 2024 OPPS/ASC rule is expected in the coming weeks.

- For more information on the proposed rule: Fact Sheet, Proposed Rule, Addendum AAA

<u>Background</u>

Under the 340B Drug Discount Program participating providers can purchase certain outpatient drugs or biologicals from manufacturers at discounted prices. In the CY 2018 Outpatient Payment Prospective System final rule, CMS changed the payment rate for 340B drugs from the average sales price (ASP) plus 6% to ASP minus 22.5%, which the agency said would more accurately show the actual costs 340B hospitals incur when acquiring 340B drugs. As required by statute, CMS implemented the change in a budget neutral manner by increasing payments to all hospitals, including non-340B hospitals, for non-drug items and services. The changes to 340B payments were in effect from CY 2018 through approximately the third quarter of CY 2022.

On June 15, 2022, the Supreme Court in *American Hospital Association v. Becerra* unanimously ruled that the payment rate changes for 340B drugs were unlawful because HHS did not conduct a survey of hospitals' acquisition costs prior to issuing the rules. On September 28, 2022, the District Court for the District of Columbia vacated the lower payment rate for 340B drugs and CMS resumed paying the default rate of ASP plus 6%. In January, the District Court ruled CMS could propose a plan to payback providers for the lower payments made between CY 2018 and CY 2022.

<u>Proposed Rule: Key Updates</u>

CMS in the proposed rule outlines two key payment mechanisms related to the 340B repayments. First, CMS proposes making single, lump sum payments to 340B hospitals that were impacted by the underpayments from 2018 to 2022. CMS estimates it will need to pay back a total of $9 billion to about 1,600 340B hospitals. CMS proposes calculations of the amounts owed to each 340B hospital. The proposed rule contains the calculations of the proposed lump sum remedy payments owed to the approximately 1,600 affected 340B covered entity hospitals in Addendum AAA, linked above.

CMS says the lump sum payments would account for beneficiary copayments that 340B hospitals did not receive from CY 2018 to 2022 and clarifies that hospitals will not be able to bill beneficiaries for coinsurance on remedy payments.

Second, CMS proposes to recoup funds from hospitals that received increased rates for non-drug items and services from 2018 to 2022 as part of the budget neutrality adjustment. These recoupments will impact both 340B and non-340B hospitals paid under the OPPS. CMS proposes to recoup those funds beginning in CY 2025 by adjusting the OPPS conversion factor for non-drug items and services by minus 0.5%. CMS says it would continue the negative adjustment until the full amount of $7.8 billion is recouped, which the agency estimates will be 16 years. CMS says providers that enrolled in Medicare after January 1, 2018, would not be impacted by the negative rate adjustment.

"We do not believe Congress intended the statute to permit regulated entities to achieve policy outcomes through litigation that would be statutorily unavailable to them through the regular rulemaking process—especially policy outcomes that increase total Medicare expenditures," the proposed rule states.

CMS is accepting comments on the proposed rule until September 5.

If you have questions, please contact Heather Meade or Heather Bell.