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

On Thursday (November 2), the Centers for Medicare & Medicaid Services (CMS) issued a final rule detailing the agency's plan for repaying about 1,700 340B hospitals $9 billion in previous cuts to hospital outpatient payments under the 340B Drug Discount Program after the Supreme Court ruled the cuts unlawful, as well as recouping funds from hospitals that received increased rates for non-drug items and services from 2018 to 2022. CMS' final rule includes an updated hospital-by-hospital breakdown of expected repayment amounts in Addendum AAA (linked below).

Overall, CMS said it believes "the best policy is the one that returns all parties as close as we can to the situation they would have been in if the 340B Payment Policy had never been adopted." While CMS acknowledges that "changes to utilization and other behaviors will leave 'some hospitals slightly better off and others slightly worse off than they would have been had the rate reduction never taken effect,' such differences are permissible variations inherent in a prospective remedy."

The final rule maintains CMS' proposal to repay hospitals in a budget neutral manner, making adjustments to the conversion factor starting in CY 2026 instead of CY 2025, as proposed. The final rule also includes a process for 340B covered hospitals to request the correction of any errors they identify in CMS' calculation of the specific remedial amount by November 30, 2023. Payments are expected at the end of CY 2023 or the beginning of CY 2024, following CMS issuing instructions to the Medicare Administrative Contractors (MACs), which will come as soon as possible after the technical corrections submission deadline has passed or after those requests are resolved. Payments will be made no later than 60 days after the MAC's receipt of instructions.

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

Background

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 (September 27, 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 the Department of Health and Human Services (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 pay back providers for the lower payments made between CY 2018 and CY 2022. CMS issued the proposed rule on July 10 and accepted comments on the agency's proposed repayment and recoupment plan.

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

CMS largely finalized the rule as proposed with only a few key changes, including delaying the start date for payment recoupment by one year and establishing a new technical correction process for affected 340B hospitals to flag potential errors in the calculation of their repayment amount.

340B remedy payments

CMS finalized its plan to make single, lump sum payments to 340B hospitals that were impacted by the underpayments from 2018 to 2022. CMS estimated it will need to pay back a total of $9.004 billion to about 1,700 340B hospitals. CMS in the final rule stated it did not have the authority to pay interest on the remedy payments.

CMS also finalized its proposal to account for beneficiary copayments that 340B hospitals did not receive from CY 2018 to 2022 in the lump sum payments and emphasized that hospitals cannot bill beneficiaries for coinsurance on remedy payments.

CMS in the final rule also updated the estimated remedy payment amounts for affected 340B covered entity hospitals contained in Addendum AAA to account for new data and address errors affected 340B hospitals flagged in their comments. CMS also added new columns to Addendum AAA to provide hospitals with more information regarding their remedy payment amount calculations and established a technical correction process that affected 340B hospitals can use to flag potential repayment amount errors. Affected 340B covered entity hospitals have until November 30, 2023, to submit their requests to outpatientpps340b@cms.hhs.gov. CMS stated that submissions must include 1) a description of the nature of the error; 2) a designated contact person; and 3) relevant supporting documentation such as claim numbers, total units, payment amount received, and date of payment. CMS warned that repayments could be delayed depending on the volume and complexity of the requests.

For hospitals that do not request corrections, CMS said they intend to issue repayment instructions to MACs for hospitals that do not request corrections shortly after the November 30th deadline, with payments following no more than 60 days after the instructions were received. They plan to issue instructions to pay hospitals who submit technical correction requests after those requests are resolved.

Budget neutrality

Despite many comments urging CMS to reconsider its plan to implement the repayment in a budget neutral manner, CMS reiterated in the final rule that it is required by statute to do so. Further, CMS noted that even in the absence of statute the agency would need to budget neutralize the remedy payments. As CMS explained, "Failing to budget neutralize the remedy payments would mean that the additional payments for non-drug items and services that were made from CY 2018 through CY 2022 … would be a windfall. … and the Trust Fund has a strong interest in recovering them."

Repayment for non-drug items and services

CMS finalized its plan to recoup funds from both 340B and non-340B hospitals that received increased rates for non-drug items and services from 2018 to 2022 by adjusting the OPPS conversion factor for non-drug items and services by minus 0.5% until the full amount of $7.8 billion is recouped, which the agency estimates will be 16 years. CMS reiterated that providers that enrolled in Medicare after January 1, 2018, would not be impacted by the negative rate adjustment.

In response to comments, CMS delayed the start of the repayment from CY 2025 to CY 2026 to give entities additional time to prepare for the new payment rates, acknowledging hospitals' current financial challenges related to workforce shortages, inflation, supply chain disruption and the lingering effects of the COVID-19 pandemic. Going forward, CMS said OPPS proposed and final rules will contain the exact impact of the reduction on OPPS payment rates.

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