

November 21, 2023

On Nov. 8, the Centers for Medicare & Medicaid Services (CMS) finalized a 340B payment remedy in response to the U.S. Supreme Court Decision in *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (2022). The case focused on whether CMS has the authority to make cuts to the 340B program under the Medicare Outpatient Prospective Payment System (OPPS). The Court found that CMS unlawfully underpaid hospitals for 340B-acquired drugs when it changed its payment policy from average sales price (ASP) plus 6% to ASP minus 22.5% in calendar year (CY) 2018.

CMS finalized the remedy as proposed to provide 340B-enrolled hospitals with a one-time, budget neutral lump sum payment. CMS will pay hospitals the difference between payments it made for 340B drugs from CY 2018 through Sept. 27, 2022, and what payments would have been had the 340B payment policy not changed.

In the proposed rule, CMS estimated that 340B hospitals received approximately \$10.5 billion less in 340B drug payments from CY 2018 through Sept. 27, 2022. However, updated claims data revealed that 340B hospitals actually received \$10.6 billion less in 340B payments over this time period. This total includes money that would have come from Medicare beneficiaries via cost sharing. CMS emphasized that Medicare will cover the cost of these beneficiary payments, and hospitals may not bill beneficiaries for coinsurance on remedy payments.

CMS realized this discrepancy in response to comments from individual hospitals suggesting that the repayment amounts provided in Addendum AAA of the proposed rule were inaccurate. Upon further review, CMS found these commenters were correct, and adjusted its total repayment amount accordingly. Anticipating potential errors in the final rule, CMS established a technical correction process for 340B hospitals to request corrections to any errors identified in CMS' calculation of remedy payments. 340B hospitals can alert CMS to potential errors in the calculation of their final lump sum repayment amount in Addendum AAA by emailing CMS at outpatientpps340b@cms.hhs.gov by 11:50 PM eastern standard time on Nov. 30, 2023.

Submissions to the technical correction process must include:

- A description of the nature of the error;
- A designated contact person for the purposes of addressing the error; and
- Relevant supporting documentation such as claim numbers, total units, payment amount received, and date of payment.

CMS reimburses hospitals for 340B-acquired drugs under the OPPS. Because the OPPS is a budget neutral system by statute, CMS increased non-drug item and service payments to all OPPS providers for CY 2018 through CY 2022 when it implemented the 340B payment policy of ASP minus 22.5%. This resulted in additional payments to all OPPS hospitals for non-drug items and services. CMS believes that as it is now correcting its unlawful underpayments to affected 340B hospitals, it must correspondingly offset OPPS payments to maintain budget neutrality.

To do this, CMS will prospectively offset OPPS payments for non-drug items and services by \$7.8 billion to maintain budget neutrality. CMS will do this by reducing all payments for non-drug items and services to all OPPS providers by 0.5% percent each year until the total offset is reached. While CMS proposed implementing this adjustment in CY 2025, it finalized an implementation date of CY 2026 in response to comments on the proposed rule. CMS estimates it will take approximately 16 years to reach the estimated \$7.8 billion it must recoup to achieve budget neutrality.

Any new hospital that enrolled in Medicare on or after Jan. 2, 2018 will be designated as a "new provider," and CMS will not

subject these hospitals to the negative 0.5% annual adjustment beginning in CY 2026. There are four hospitals in Illinois designated as “new providers,” and they can be found in [Addendum BBB](#).

CMS [estimates](#) that Illinois 340B hospitals will receive a total lump sum payment of approximately \$335 million in response to this remedy. CMS will instruct Medicare Administrative Contractors (MACs) to issue lump sum payments to 340B hospitals within 60 calendar days of the MACs receiving repayment instructions. CMS anticipates MACs will begin making payments by the end of CY 2023 or beginning of CY 2024.

Finally, CMS commented on concerns regarding the treatment of 340B payments by Medicare Advantage (MA) plans. CMS referred commenters to a [memo](#) issued on Dec. 20, 2022. Specifically, MA plans must pay non-contract providers or facilities at least the amount they would have received under original Medicare payment rules. However, CMS may not require MA plans to contract with a particular healthcare provider or use specific pricing structures with their contracted providers. As such, MA plans that contract with 340B hospitals can negotiate the terms and conditions of payment directly with that hospital, and CMS cannot interfere with the payment rates set in such contracts.

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Illinois Health and Hospital Association