

Issue Brief

FEDERAL ISSUE BRIEF



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CMS Finalizes “Remedy” for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022

The Centers for Medicare & Medicaid Services (CMS) have issued a final rule that is intended to provide a remedy in light of the United States Supreme Court’s decision in *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (2022) relating to the adjustment of Medicare payment rates for drugs acquired under the 340B Program from calendar year (CY) 2018 through September 27, 2022.

A copy of the 129-page rule is currently available at: <https://public-inspection.federalregister.gov/2023-24407.pdf>. The rule is scheduled for publication on November 8.

In 2018, CMS adopted a policy to pay an adjusted amount of Average Sales Price (ASP) minus 22.5% for certain separately payable drugs or biologicals acquired through the 340B Program instead of ASP + 6.0%. To comply with statutory budget neutrality requirements under the OPSS, CMS made a corresponding increase to payments to all hospitals (340B hospitals and non-340B hospitals) for non-drug items and services, which was in effect from CY 2018 through CY 2022.

CMS notes that critical access hospitals are not paid under the OPSS, and therefore are not subject to the OPSS 340B drug payment adjustment policy. CMS also exempted rural sole community hospitals, children’s hospitals, and PPS-exempt cancer hospitals from the payment adjustment change.

Final Decision

CMS is finalizing its proposed policy. In particular, CMS is making lump sum payments, calculated as the difference between what an affected 340B covered entity hospital received for 340B-acquired drugs during the time period at issue and what they would have received for 340B-acquired drugs if the 340B adjustment had not been in place.

Remedy Payment Adjustment for 340B-Acquired Drugs from CY 2018 through September 27, 2022

In the CY 2023 OPSS/ASC final rule CMS finalized a policy reversing the 340B Payment Policy. To do so, it first provided that drugs acquired through the 340B Program would be paid at the default rate (generally ASP plus 6.0%) for CY 2023. Second, to ensure budget neutrality for CY 2023 OPSS payment rates as required by statute, CMS finalized a payment reduction of 3.09% to the 2023 OPSS conversion factor. This 3.09% reduction for CY 2023 offsets the prior increase of 3.19% that was applied to the conversion factor by the 340B Payment Policy in CY 2018.

Reduction in Drug Payments to Affected 340B Covered Entity Hospitals in CY 2018 through September 27, 2022

CMS estimates 1,649 340B covered entity hospitals were paid at the 340B payment rate for CY 2018 through September 27, 2022. CMS estimates that these hospitals received approximately \$10.6 billion less in 340B drug payments (including money that would have been paid by Medicare and money that would have come from beneficiaries as copayments) than they would have for drugs provided in CY 2018 through September 27th of 2022 had the 340B policy not been implemented.

CMS estimates that 340B providers have already received \$1.6 billion in remedy payments through reprocessed claims for 340B drugs provided from January 1, 2022, through September 27, 2022. CMS estimates the remaining remedy amount that affected 340B covered entity hospitals have not yet received as a result of this policy is \$9.0 billion

Accordingly, CMS will make total lump sum payments in the amount of \$9.0 billion as a result of this final rule.

OPPS Non-Drug Item and Service Payments from CY 2018 through CY 2022

To ensure budget neutrality for CY 2023 OPPS payment rates as required by statute, CMS finalized a reduction of 3.09% to the 2023 OPPS conversion factor. This 3.09% reduction for CY 2023 offsets the prior increase of 3.19% that was applied to the conversion factor when CMS implemented the 340B payment policy in CY 2018.

CMS will reverse the accompanying increase in the conversion factor for CYs 2018 through 2022 that was solely attributable to the adoption of the 340B payment policy. In order to reduce the burden on providers of offsetting this amount required to maintain budget neutrality, estimated to be \$7.8 billion, CMS will implement this adjustment prospectively.

Beginning in CY 2026, CMS will reduce all payments for non-drug items and services to all OPPS providers, except new providers, by 0.5% each year until the total offset is reached (approximately 16 years).

CMS is finalizing its policy to instruct the MACs to remit remedy payments to affected 340B covered entity hospitals as proposed. These payments will be a one-time lump sum payment to the hospital within 60 calendar days of the MAC's receipt of the instruction.

Comment

This is a long rule with too much redundancy and history. The following is from the rule beginning on page 109.

Summary of Finalized Policy

CMS is finalizing "the proposed remedy for the 340B Payment Policy for CYs 2018-2022, with the one exception that we are changing the implementation date of the 0.5% adjustment from CY 2025 to CY 2026." "CMS will make a one-time lump sum payment to each affected 340B covered entity hospital calculated as the difference between what the affected 340B covered entity hospital received for 340B-acquired drugs during the time period at issue and approximately what they would have received for 340B-acquired drugs if the 340B adjustment had not been in place, which includes what the affected 340B covered entity hospital would otherwise have been paid by the beneficiary. The amount of the lump sum payment that has been calculated for each affected 340B covered entity hospital is listed in Addendum AAA."

"Following the deadline to submit a request for technical correction to the amount listed in Addendum AAA, we will issue instructions to the Medicare Administrative Contractor (MAC) for each affected 340B covered entity hospital that has not submitted a request for technical correction by the deadline discussed in this rule. We will instruct the MAC to issue a one-time lump sum payment to those hospitals in the amount listed in Addendum AAA within 60 calendar days of the MAC's receipt of the instruction. We will instruct MACs to pay hospitals that submit a request for technical correction through a similar process after the technical correction process is completed, and the payment amount for those providers will be based on the result of the technical correction process. The lump sum payments do not include interest. In aggregate, the lump sum payments we calculate here will total \$9.0 billion and will include a portion equivalent to the amount that beneficiaries, through cost-sharing, would have paid hospitals."

"Beginning in CY 2026, we will reduce all payments for non-drug items and services to all OPPS providers, except new providers (hospitals with a CMS CCN effective date of January 2, 2018, or later), by 0.5% each year until the total estimated offset of \$7.8 billion is reached. We currently estimate that the payment decrease will be completed after approximately 16 years. To implement this reduction and exception for new providers, we are finalizing the proposed regulation text changes at §

419.32(b)(1)(iv)(B) as proposed, except for changing the implementation date of the 0.5% reduction from CY 2025 to CY 2026.”

Final Comment

It is interesting to note that CMS says it will be making prospective adjustments for the required retroactive decision on the issue at hand. So why does CMS constantly say it is not prudent and not wise to make prospective adjustments for retroactive errors in forecasting estimates?