# CMS Releases Proposed Remedy for 340 B-Acquired Drugs Purchased in Cys 2018–2022

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On July 7, 2023, the Centers for Medicare and Medicaid Services (CMS) released the proposed rule, Hospital Outpatient Prospective Payment System: Remedy for 340B-Acquired Drugs Purchased for Calendar Years 2018–2022, to address how CMS plans to restore payments to hospitals affected by prior CMS policy to reduce Medicare payments on 340B drugs for most 340B hospitals paid under the Outpatient Prospective Payment System (OPPS) from January 1, 2018, through September 27, 2022.

## IN DEPTH

CMS intends to implement two key adjustments to remedy the 340B reimbursement rate reductions. First, CMS proposes to make one lump-sum payment to affected 340B hospitals based on the difference between what individual affected hospitals were paid at the reduced payment rate of average sales price (ASP) minus 22.5% and what the hospitals would have been paid at the full OPPS rate of ASP plus 6%. CMS estimates the total amount of these lump-sum payments to be approximately $9 billion. Second, CMS proposes to recoup $7.8 billion in corresponding “budget neutrality” payments made on all other items and services to all hospitals paid under OPPS through a 0.5% annual reduction in the OPPS conversion factor beginning in calendar year (CY) 2025.

Comments for the proposed rule are due September 5, 2023.

We previously analyzed the 340B payment reductions and litigation in a series of articles:

- CMS Finalizes 340B Payment Provisions in 2023 OPPS Final Rule
- District Court Vacates 340B Cuts, but Don't Expect Immediate Payment Rate Restoration
- DC Circuit Upholds OPPS Reimbursement Reductions for 340B Drugs
- July Surprise – Supreme Court Agrees to Review Medicare Payment Cuts to 340B Drugs
- Court Issues Permanent Injunction Blocking Medicare 340B Payment Cuts
- CMS Cuts Payments for Most 340B Drugs

## IN DEPTH

**Background**

Beginning in 2018, CMS implemented a reduction to payments for 340B drugs to most 340B hospitals reimbursed by Medicare under OPPS, lowering the reimbursement amounts from ASP plus 6% to ASP minus 22.5%. Prospective payment system (PPS)-exempt cancer hospitals, PPS-exempt children's hospitals and rural sole community hospitals are paid under OPPS, but were not subject to the payment cuts.

As required by the Social Security Act, the payment reduction was implemented in a "budget neutral" manner, such that the estimated amount of the OPPS payment reduction for 340B drugs was used to increase payments on other items and services paid to all hospitals under OPPS. The 340B payment cuts were immediately subject to litigation, for which additional information can be found in the above-referenced articles. Ultimately, the US Supreme Court found that the 340B payment cuts were not consistent with federal laws governing Medicare payments for drugs under OPPS and the payment rule was vacated.

In the 2023 OPPS Final Rule, CMS finalized its proposal to return payments for 340B drugs to the full OPPS payment rate of ASP plus 6%. However, the 2023 OPPS Final Rule did not address remedies for payments made between 2018 and 2022. This proposed rule is intended to address the outstanding issue of remedies.

**Remedy for the 340B-Acquired Drug Payment Policy for CYs 2018–2022 Proposed Rule: Lump Sum**

In this proposed rule, CMS proposes a remedy for the historical 340B payment reduction in two parts: (i) one lump-sum payment to each affected 340B hospital, which covers the difference in what the hospital was paid under the reduced payment rate for 340B drugs and what it should have been paid under the full OPPS payment rate; and (ii) a decrease in the OPPS conversion factor by 0.5% each year for most hospitals paid under OPPS, beginning in CY 2025, until the amount of payments under the reduced conversion factor offsets the amount of the increased budget neutrality payments made in connection with the reduced 340B drug payments.

Specifically, CMS proposes to calculate the amount that each affected 340B hospital would have been paid for 340B drugs under the full OPPS rate from January 1, 2018, through September 27, 2022 (the last date that CMS imposed the reduced payment rate), and then subtract that figure from the amount that the hospital was actually paid for such drugs during the same period. CMS believes that this approach will come as close as possible to making the affected hospitals whole as to the 340B payment cuts, without manually reprocessing all claims during the period that the cuts were in place. Under this proposed methodology, CMS estimates that it will make these lump sum payments totaling $9 billion to 1,649 340B hospitals.

Of note, while CMS estimates that from CY 2018 through September 27, 2022, affected hospitals received $10.5 billion less in 340B drug payments than they would have without the vacated policy, CMS estimates that affected hospitals have already been paid $1.5 billion in true-up payments due to claim reprocessing at the higher rate that occurred on most claims for 340B drugs during CY 2022.

CMS intends to implement the lump-sum payment by issuing instructions to the Medicare Administrative Contractors (MACs) to issue payments within 60 calendar days of a MAC's receipt of instruction, which CMS expects to be provided in late 2023 or early 2024. CMS is proposing to not apply interest to the lump-sum remedy payments, but is proposing to incorporate the necessary increased payments for beneficiary cost-sharing amounts into the payments.

**Remedy for the 340B-Acquired Drug Payment Policy for CYs 2018–2022 Proposed Rule: Offset by Decreasing the OPPS Conversion Factor 0.5% Each Year**

Due to statutory budget neutrality requirements under OPPS, when CMS reduced payments for 340B drugs beginning CY 2018, CMS increased payment to all hospitals for other items and services paid under OPPS. CMS estimates that an additional $7.8 billion was paid under this budget neutrality adjustment between CY 2018 and CY 2022. The differential between the $7.8 billion in increased budget neutrality payments and $10.5 billion in reduced payments for 340B drugs reflects the lack of accuracy in CMS's budget neutrality calculation, which was made prior to the implementation of the adjustments in 2018 and was not recalculated or revised during the period that the cuts and corresponding increased payments were in place.

CMS now proposes, beginning in CY 2025, to reduce all payments for non-drug items and services to all OPPS providers, except "new providers" enrolled in Medicare after January 1, 2018, by 0.5% each year until the estimated overpayment amount of $7.8 billion is offset. CMS currently expects this process will take approximately 16 years.

## ANALYSIS

Several issues remain outstanding, following the release of the proposed rule:

A key concern is whether CMS' methodology to recoup amounts paid at higher rates for non-drug items and services provided from CY 2018 through 2022 will actually reset payments to the amounts that would have been received by hospitals had the 340B payment cuts never been implemented. CMS acknowledges that the reduced conversion factor will not precisely recoup amounts paid to each hospital under the prior budget neutrality adjustment. The extent to which the recouped payments match the prior payments in excess of what would have otherwise been received will be dependent on each hospital's historic and future mix of items and services subject to the corresponding adjustments. CMS addresses this concern by stating that some imprecision is inherent in budget neutrality calculations, and the alternative would require that CMS recalculate the additional amount that each hospital received under the prior policy and then apply a specific reduction to each hospital, a process that CMS believes would impose significant burdens and payment delays.

CMS decided against collecting a lump-sum payment recoupment from hospitals to not overwhelm hospitals impacted by this remedy and to partially account for reliance interests in the money paid to hospitals for non-drug items and services over the applicable period. To reduce the impact further, CMS could decide to impose the offset adjustment at smaller decreases to the conversion factor and extend the reduction for a longer period of time. CMS invites comments on the estimated budget neutrality offset calculations, the annual percent reduction method, and whether an alternative option would be appropriate. CMS is also asking for feedback on the alternative timelines for maintaining budget neutrality and whether hospitals need additional time (e.g., from starting the effective date of the prospective offset policy beginning CY 2025 to CY 2025) to prepare following any finalized policy.

In addition, due to the CY 2018 OPPS rule that cut 340B payments but ultimately increased non-drug items and services by 3.19% for all OPPS providers, beneficiaries paid more in cost sharing for these non-drug items and services. The proposed rule is silent on whether CMS is quantifying or returning these payments in this rule, although the application of the reduced conversion factor will correspondingly reduce beneficiary cost-sharing obligations. CMS explicitly addresses their approach to beneficiary cost-sharing obligations as to the lump sum payments, but not as to the future adjustments to offset the budget neutrality payments.

Finally, the proposed rule is silent on whether and how CMS expects Medicare Advantage plans to address past payments to 340B hospitals. The issue implicates the contracts between hospitals and Medicare Advantage plans. Hospitals should review any contracts they have with Medicare Advantage plans in considering whether to submit comments in response to the proposed rule.

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