Proposed Rule on Remedy to 2018–2022 340B-Acquired Drug Payment Policy Would Reduce Non-Drug Outpatient Payments by 0.5% for 16 Years

Insights 07.10.23

July 14, 2023 Update: The Proposed Rule has been published in the Federal Register, and the comment deadline is September 5, 2023. See the published version here.

On July 7, 2023, the Centers for Medicare & Medicaid Services (CMS) released its long-awaited proposal to remedy the 340B-acquired drug payment policy for Calendar Years (CY) 2018–2022 following the Supreme Court's decision in *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (2022).

Pursuant to Section 340B of the Public Health Service Act, participating hospitals and providers may purchase certain drugs and biologicals from manufacturers at discounted prices. In the Calendar Year (CY) 2018 Outpatient Prospective Payment System/Ambulatory Surgery Center (OPPS) Final Rule, and applicable through 2022, CMS lowered the payment rate for certain drugs or biologics acquired through the 340B program from the statutory default—average sales price (ASP) plus 6 percent—to ASP minus 22.5 percent. [1] CMS explains that their reason for lowering payments for 340B drugs was to "better, and more appropriately, reflect the resources and acquisition costs that …hospitals incur." [2] To maintain budget neutrality, CMS also implemented a 3.2 percent payment increase for non-drug outpatient items and services based on the estimated impact of the 340B drug payment policy.

Last June, the Supreme Court unanimously ruled in *American Hospital Association v. Becerra* that the differential payment rate for 340B-acquired drugs was unlawful due to the agency's failure to conduct a survey of hospitals' acquisition costs under the relevant statute. Following remand, on September 28, 2022, the U.S. District Court for the District of Columbia prospectively vacated the CY 2022 differential payment rates for all 340B-acquired drugs in effect for the remainder of 2022. On January 10, 2023, the District Court remanded to CMS to craft a remedy in light of the Supreme Court's decision for CY 2018 through September 27, 2022.

All CY 2022 claims for 340B-acquired drugs paid on or after September 28, 2022 were paid at the statutory default rate, and CMS's CY 2023 OPPS Final Rule adopted the default ASP plus 6% payment rate for 340B-acquired drugs payable under the OPPS. CMS adopted a

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corresponding 3.09% reduction to the CY 2023 OPPS conversion factor for non-drug payment rates to eliminate the prospective impact of the 2018 budget neutrality payment increase.

The newly-released Proposed Rule describes CMS's proposed remedy for the agency's adjustments to 340B drug payments from CY 2018 through September 27, 2022. *Comments on the Proposed Rule are due by September 5, 2023.*

Proposed Remedy for 340B Drug Payment Adjustments in CY 2018 through September 27th of 2022: Lump Sum Payments

To remedy the reduced payment rates for 340B-acquired drugs in CY 2018 to September 27, 2022, CMS proposes to make a one-time lump sum payment to 340B hospitals. CMS estimates that OPPS drug payments to 340B providers were reduced by approximately $10.5 billion (including both Medicare and copayment dollars) under the 340B drug payment policy. [3] CMS believes these providers have already received an estimated $1.5 billion in remedy payments through reprocessed claims provided in 2022. Thus, CMS estimates that the remaining remedy amount is approximately $9 billion (including $1.8 billion in uncollected beneficiary copayments). [4]

Under the Proposed Rule, each impacted provider would receive from its Medicare Administrative Contractor a lump sum payment based on the difference between the amount that the provider would have been paid if the 340B payment policy had not been in effect and the amount that the provider was actually paid for 340B-acquired drugs, based on claims data during the time period at issue. The Proposed Rule includes calculations of the amounts owed under this methodology to each affected 340B provider in Addendum AAA.

Budget Neutrality Proposal: 0.5% OPPS Payment Reduction for Sixteen Years

In the Proposed Rule, CMS characterizes the budget neutrality adjustments that all hospitals received in CYs 2018–2022 for non-drug item and service payments as "a windfall—payments the hospitals should not have received but did anyway." CMS thus proposes to effectively recoup the budget neutrality adjusted payments that CMS made to all providers between 2018 and 2022 for non-drug items and services, "[t]o comply with budget neutrality and restore the situation as closely as reasonably possible to the state that would exist" if the challenged 340B payment policy had not been in effect between 2018 and 2022.

CMS estimates that the agency will need to prospectively recover $7.8 billion in OPPS payments. CMS thus proposes to reduce OPPS payments for non-drug items and services by 0.5 percent beginning in 2025, until the aggregate amount is recouped. CMS estimates this recoupment will take approximately 16 years to complete. The approximately 300 "New Providers" that were enrolled in Medicare after January 1, 2018, however, would be exempted from this payment reduction. These "New Providers" are identified in Addendum BBB.

CMS invites comments on its overall remedy proposal, including the agency's estimated budget neutrality calculations, methodology, and timeline, the definition and exclusion of new providers, and whether alternative options (discussed below) would be appropriate.

Notwithstanding this present request for comments, in 2019, CMS also solicited, and received, comments on how to structure a remedy, including how such remedy "could produce a result equitable to hospitals that do not acquire drugs through the 340B program while respecting the budget neutrality mandate." Some commenters strongly opposed any budget neutral remedy, noting that any such recoupment effort would be inconsistent with the prospective nature of the OPPS, judicial precedent supports an agency determination that budget neutrality is not necessary and CMS's statutory authority does not permit it to revisit budget neutrality if the agency's estimates of money owed for a prior year turn out to be incorrect. [5]

Alternative Options Considered

CMS notes that it also considered, but is not proposing, the following three alternative remedy options:

- First, CMS considered, but rejected, the option to **make additional payments to affected 340B hospitals without reducing all non-drug OPPS payments**. CMS states in the Proposed Rule that it believes the provisions providing it authority to make 340B remedy payments are subject to budget neutrality requirements, and, "even if not statutorily required," a budget neutrality adjustment is "warranted as a matter of sound public policy." CMS solicits public comments on their proposed interpretation of their statutory budget neutrality obligations, equitable payment authorities, and recoupment authority.
- Second, CMS similarly rejected the option of **full claims reprocessing** of all OPPS claims for 340B-aquired drugs and non-drug items and services from 2018–September 27, 2022. This option "would impose an immense administrative burden on CMS, its contractors, and providers," and therefore CMS deemed the approach not feasible in this case.
- Finally, CMS considered and rejected **a one-time aggregate payment adjustment or recoupment (as applicable)** for each OPPS provider that accounts for the impact of the 340B drug payment policy that was in place from January 1, 2018, to September 27, 2022, as well as the budget neutrality adjustment that was in place for all of 2018 through 2022. Although CMS states that this approach would have satisfied its budget neutrality concerns, it has the flexibility to avoid the substantial burden on hospitals and beneficiaries that would flow from the immediate and often large retroactive recoupments from the majority of OPPS hospitals under this alternative.

Timeline and Public Comments

CMS anticipates issuing the Final Rule before the CY 2024 OPPS/ASC Final Rule is published in Fall 2023. The Agency proposes to make the additional 340B payments at the end of CY 2023 or the beginning of CY 2024.

[1] For the full CY 2018 Final Rule, *see* Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 59,216, 59,354–371 (Dec. 14, 2017).

[2] 82 Fed. Reg. at 59,355.

[3] CMS states that it will update the estimated figures in the final rule as they continue to receive 2022 claims data.

[4] CMS emphasizes that 340B covered entity hospitals may not bill beneficiaries for coinsurance on remedy payments, and would consider appropriate administrative action for providers who do so.

[5] Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 84 Fed. Reg. 61,142 61,325, 61,327 (Jan. 1, 2020).

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