

Vizient Office of Public Policy and Government Relations

Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022

November 8, 2023

Background & Summary

On November 2, the Centers for Medicare and Medicaid Services (CMS) released a [Final Rule](#) that describes the remedy and approach the agency will take to comply with the [Supreme Court's decision](#) in *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (2022). In the decision, the Supreme Court ruled in favor of 340B hospitals, finding that CMS improperly reduced Medicare payment rates for drugs acquired under the 340B Program for calendar year (CY) 2018 through September 27, 2022.

There are two key components to the remedy, a lump sum payment and longer-term negative outpatient prospective payment system (OPPS) payment adjustment. For the lump sum payment, CMS finalized a policy to provide the difference between what 340B hospitals were paid for 340B drugs (e.g., average sales price (ASP) minus 22.5%) from CY 2018 through September 27, 2022, and what they would have been paid had the reductions not been applied (e.g., ASP plus 6%). CMS estimates \$9 billion will be distributed by early CY 2024.

CMS finalized a longer-term -0.5% adjustment to the OPPS conversion factor over approximately 16 years because it believes the prior increases to the conversion factor, provided for non-drug items and services for CY 2018-2022 for budget neutrality reasons, should be offset. Based on the most recent data, CMS estimates that there was an additional \$7.8 billion in additional spending on non-drug items and services due to the policy. CMS finalized that the prospective offset would start in CY 2026.

The final rule is effective January 8, 2024, and CMS makes clear that payments will not be made until the rule is effective. Medicare Administrative Contractors (MACs) are to issue a one-time lump sum payment within 60 calendar days of the MAC's receipt of CMS instructions to make the payment. Information regarding the expected payment amount to impacted providers is in [Addendum AAA](#).

Proposed Lump Sum Payment

Payment Amount and Timing

Although CMS estimates that approximately \$9 billion will be distributed, the agency notes that the total additional payment is \$10.5 billion, but this is offset by \$1.5 billion in remedy payments that providers have already received due to some claims having already been reprocessed.¹ However, as noted [below](#), this amount will be prospectively offset by \$7.8 billion.

To determine the amount CMS will pay each 340B hospital, CMS provides a data file containing the calculation of the amounts (see [Addendum AAA](#)). MACs are to issue a one-time lump sum payment

¹ Since 340B providers have already received \$1.5 billion in remedy payments since some claims for 340B drugs provided from January 1, 2022 – September 27, 2022 were already reprocessed, CMS finds approximately \$9.0004 billion is outstanding to 340B providers.

within 60 calendar days of the MAC's receipt of the instruction from CMS to make the payment. CMS notes that no payment may be transmitted before the Final Rule is effective, which is 60 days after the date of the Final Rule's publication in the Federal Register. Based on this information, impacted providers may expect payment in early 2024.

CMS also finalized a technical corrections procedure to alert the agency of issues regarding the payment amount noted in Addendum AAA. Such alerts should be emailed to CMS (outpatientpps340B@cms.hhs.gov) by 11:59 pm on Nov 30, 2023. Submissions must include (1) a description of the nature of the error; (2) a designated contact person for the purposes of addressing the error; and (3) relevant supporting documentation such as claim numbers, total units, payment amount received, date of payment. It is important to note that submitting such a request could result in a delay of payment to the hospital.

In the Final Rule, CMS makes clear it is not paying interest on the remedy payments.

Proposed Negative OPPS Payment Adjustments for Future CYs

Budget Neutrality

For the OPPS CYs 2018-2022, CMS provided a budget neutrality adjustment to increase the rate for non-drug items and services by 3.19%, due to the reduction in reimbursement for 340B-acquired drugs. As a result, CMS believes an additional \$7.8 billion in spending on non-drug items and services occurred during that period. To recover these funds, beginning in CY 2026, CMS will reduce payment for non-drug items and services to all OPPS providers, except new providers, by 0.5% each year until the total offset is reached. CMS anticipates that it will take 16 years for the total offset to be reached.

New Provider Exclusion

Consistent with the Proposed Rule, CMS finalized policy to designate any hospital that enrolled in Medicare on or after January 2, 2018 as a "new provider" for purposes of the offset to future conversion factors. As a result, CMS will pay these "new providers" the rate for non-drug items and services that would apply in the absence of the conversion factor adjustment implemented due to the 340B Payment Policy remedy. [Addendum BBB](#) of the Final Rule lists providers that CMS believes meet the definition of a "new provider".

Medicare Advantage

In the Final Rule, CMS acknowledges stakeholders' concerns regarding Medicare Advantage Organization's (MAO's) compliance with the remedy. CMS refers stakeholders to a December 2022 memorandum to MAOs where CMS "clarified that for Medicare Advantage, MAOs must pay non-contract providers or facilities for services and items at least the amount they would have received under Original Medicare payment rules ... CMS may not require MAOs to contract with a particular healthcare provider or use particular pricing structures with their contracted providers. Therefore, MAOs that contract with a provider or facility eligible for 340B drugs can negotiate the terms and conditions of payment directly with the provider or facility and CMS cannot interfere in the payment rates that MAOs set in contracts with providers and facilities."

What's Next?

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this Final Rule. Although CMS is not expected to make changes to this Final Rule, stakeholder feedback still plays an important role in shaping future policy. We encourage you to reach

out to our office if you have any questions; please direct your feedback to [Jenna Stern](#), associate vice president, regulatory affairs and public policy, in Vizient's Washington, D.C. office.