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**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

**July 14, 2023**

## Background & Summary

On July 7, the Centers for Medicare and Medicaid Services (CMS) released a Proposed Rule that describes the proposed 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 proposed remedy, a lump sum payment and longer-term negative outpatient prospective payment system (OPPS) payment adjustments. For the lump sum payment, CMS proposes 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, if the Proposed Rule is finalized.

CMS proposes longer-term negative OPPS payment adjustments 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 during CY 2018 to CY 2022. CMS acknowledges that the proposed lump sum payment to 340B hospitals exceeds the amount that needs to be offset as a result of additional spending on non-drug items and services. CMS does not propose to directly recoup funds providers already received. Instead, CMS proposes a -0.5% adjustment to future payments beginning in CY 2025 and until a total offset is reached. CMS estimates this negative adjustment will be in place for 16 years.

Comments are due **no later than September 5, 2023**. Vizient looks forward to working with providers to help inform our letter to the agency.

## Proposed Lump Sum Payment

### Payment Amount

CMS estimates that the total additional payment that providers will receive due to the Supreme Court's decision is $10.5 billion, and as noted below, this amount is proposed to be prospectively offset by $7.8 billion. In the Proposed Rule, CMS indicates that these estimates may change as it continues to receive updated CY 2022 claims data. Also, CMS indicates that 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. As a result, CMS finds approximately $9 billion is outstanding to 340B providers.

To determine the amount CMS proposes to pay each 340B hospital, CMS provides a data file containing the calculation of the amounts (see Addendum AAA). To calculate estimated aggregate payments, CMS isolated 340B drugs assigned the status indicator "K" (non-pass-through drugs and

non-implantable biologics, including radiopharmaceuticals) and billed with the JG modifier. CMS then calculated the difference between the CY 2018-2022 340B payment rate and the 340B rate proposed (i.e., the difference between ASP plus 6% and ASP minus 22.5%; a similar process was used for payment amounts based on WAC[1] or AWP[2]). **CMS seeks comment on the accuracy of the data in Addendum AAA, particularly with respect to the estimated amount of remedy payment due to each hospital and the methodology the agency used.**

CMS notes that it does not believe it has authority to pay interest on the remedy payments.

### Anticipated Timing of Remedy Payments

If the agency finalizes the Proposed Rule, then it would aim to make the lump sum payments at the end of CY 2023 or beginning of CY 2024. Also, once a final rule is released, CMS indicates it will provide Medicare Administrative Contractors (MACs) with instructions regarding the lump sum payments and it would require that MACs make payments within 60 calendar days of receiving those instructions. CMS notes that MACs would continue to follow normal accounting processes for collecting repayment amounts, which may impact the provider's net payment.

### Beneficiary Cost Sharing

In the Proposed Rule, CMS clarifies the $9 billion outstanding payment amount includes $1.8 billion, which is equivalent to the amount that covered entity hospitals would have collected from beneficiaries for the 340B-acquired drugs if the reductions had not been in place. Given the agency's proposal to reduce future OPPS payments by 0.5% beginning in CY 2025, CMS anticipates beneficiaries will generally have lower coinsurance for non-drug items and services. Also, CMS clarifies that, if finalized, affected 340B hospitals may not bill beneficiaries for copayments on remedy payments and that the agency would consider appropriate administrative action for providers who do. **CMS seeks comment on this proposed approach to account for beneficiary cost sharing.**

## Proposed Negative OPPS Payment Adjustments for Future CYs

### CMS Authority and Statutory Requirements

In the Proposed Rule, CMS references various portions of the Social Security Act[3] and notes that it believes the agency has the authority to make remedy payments, and that certain portions of statute require budget neutrality when payment adjustments to the OPPS are made. CMS indicates that the remedy payments may be understood to be a payment adjustment and therefore subject to budget neutrality constraints. In addition, CMS notes that even if budget neutrality adjustments are not statutorily required, it believes such an adjustment is warranted to preserve the Medicare Supplementary Insurance Trust Fund, especially since the amount of the one-time lump sum payment is a substantial fraction of total OPPS spending for any one calendar year. **CMS seeks comment on the agency's interpretation of its statutory budget neutrality obligations and other possible authorities that may be applicable.**

### 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 and avoid an "unwarranted windfall to providers",

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[1] For drugs priced using WAC, CMS calculated the difference between WAC minus 22.5% and WAC plus 3% or 6%, as applicable.
[2] For drugs priced using AWP, CMS calculated the difference between 69.46% of AWP and 95% of AWP.
[3] CMS believes the authority to make remedy payment is provided under sections 1833(t)(2)(E) and 1833(t)(14) of the Act, along with the agency's retroactive rulemaking authority in section 1871(e)(1)(A) of the Social Security Act.

CMS proposes to offset the additional payments to maintain budget neutrality as part of the remedy. Specifically, CMS proposes at the beginning in CY 2025 to reduce all 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. Table 1 of the Proposed Rule (pg. 39) provides an illustration of the proposed adjustments to future conversion factors. **CMS welcomes comments on the proposed annual reduction and additional alternative timelines (e.g., 5, 10 or 15 years). Also, CMS invites comments regarding whether hospitals need additional time to prepare for payment reductions (e.g., delaying reductions by one year from CY 2025 to CY 2026).**

Although CMS acknowledges the budget neutrality calculations for CY 2018-2022 increased payments for non-drug services by less than the amount that CMS decreased payments for 340B drugs, the agency CMS makes clear that it is not proposing, at this time, to revise retroactively its estimated expenditures for CY 2018-2022.

### New Provider Exclusion

In the Proposed Rule, CMS believes that any hospital that enrolled in Medicare after January 1, 2018 did not receive the full amount of the increased non-drug item and service payments made during CY 2018-2022 that they otherwise would have received if enrolled prior to that date. As a result, CMS proposes to designate any hospital that enrolled in Medicare after January 1, 2018 as a "new provider" for purposes of the offset to future conversion factors.

To identify a new provider, CMS proposes to use the date of enrollment in Medicare as the provider's CMS certification number (CCN) effective date. Providers that meet the definition of new provider would be excluded from the prospective payment adjustment. Addendum BBB of the Proposed Rule lists the approximately 300 providers (of 3,900 OPPS providers) that CMS believes meet the definition of new provider. CMS clarifies that the term new provider is not intended to include providers that were enrolled in Medicare before January 1, 2018, and subsequently had a change in ownership that resulted in a new CCN. CMS acknowledges that the proposed exclusion results in exempting some hospitals receiving the 340B lump sum payment from the proposed future negative payment adjustment. **CMS seeks comment on the proposed definition of new provider and the proposal to exempt new providers from future annual adjustments to the conversion factor. CMS also seeks comment on whether there are any other easily identifiable categories of providers who should be similarly exempted from the annual adjustment to the conversion factor.**

## Alternatives Considered

In the Proposed Rule, CMS outlines various alternative policies it considered, such as requiring claims to be reprocessed and one-time aggregate payment adjustments for each provider for the period of CY 2018 through September 27, 2022. Reasons CMS references for not proposing these options include significant administrative burden and excessive costs to the Medicare Trust Fund.

## What's Next?

CMS anticipates publishing a final rule before the end of CY 2023, but it is not certain. The comment period closes on September 5, 2023.

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this Proposed Rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. Please direct your feedback to Jenna Stern, associate vice president, regulatory affairs and public policy, in Vizient's Washington, D.C. office.