PUBLICATION

CMS Issues Proposed Remedy for 340B-Acquired Drug Payment Policy

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On Friday, July 7, The Centers for Medicare & Medicaid Services (CMS) published its proposed rule to remedy payment rates the Supreme Court held invalid in a ruling last summer. A key component of the remedy is maintaining budget neutrality which CMS claims is required by statute. CMS is proposing to reduce future non-drug item and service payments by adjusting the Outpatient Prospective Payment System (OPPS) conversion factor. Therefore, the proposed policy will affect all hospitals paid under the OPPS, regardless of their participation in the 340B Drug Program.

Background

The Supreme Court's decision in *American Hospital Association v. Becerra* (142 S. Ct. 1896 [2022]) unanimously ruled that the differential payment rates for 340B-acquired drugs were unlawful because, prior to implementing the rates, Health and Human Services (HHS) failed to conduct a survey of hospitals' acquisition costs under the relevant statute. Following the Supreme Court's ruling, the District Court of Columbia vacated the differential payment rates for 340B-acquired drugs going forward. As a result, all CY 2022 claims for 340B-acquired drugs paid on or after September 28, 2022, were paid at the default rate of Average Sales Price plus six percent. The CY 2023 OPPS/Ambulatory Surgery Center (ASC) final rule included CMS' announcement that it would address the remedy for 340B drug payments from 2018-2022 prior to the release of the CY 2024 proposed rule.

Lump Sum Payments To Affected Providers

Between CY 2018 through CY 2022, CMS estimates that OPPS 340B providers received $10.5 billion less in 340B drug payments than they would have without the 340B policy. However, CMS affirms that affected 340B providers have already received $1.5 billion through CY 2022 claims processing at the higher default payment rate. As a result, the proposed one-time lump sum payment amount to all affected 340B providers is $9 billion for claims covering CY 2018 through CY 2022.

In the proposed policy, CMS outlines the following process for calculating the amount of payment owed to each affected 340B covered entity hospital. The proposed formula will calculate the amount a hospital would have been paid under the OPPS from CY 2018 through September 27 of CY 2022 for drugs the hospital acquired through the 340B Program had that policy not been in effect. CMS will then subtract from this total, the amount each affected 340B covered entity hospital was paid under the OPPS for 340B-acquired drugs during the period of CY 2018 to September 27 of CY 2022.

The following is the CMS illustrative example of the proposed repayment calculation. Based on claims data from CY 2018 through September 27 of CY 2022 for claims that have been processed and OPPS payments already made, CMS would calculate that a particular 340B-covered entity hospital would have been paid an estimated $10 million for 340B drugs had that 340B payment policy not been in effect during that time. Then, based on claims data for the same hospital from the same time, CMS would calculate that the hospital was actually paid $7.31 million for 340B drugs from CY 2018 through September 27 of CY 2022. The difference between these two amounts – $2.69 million – would be the amount of the additional lump sum payment the 340B covered entity hospital would receive.

The remitting process for the lump sum payment would be through the hospital's Medicare Administrative Contractor (MAC). CMS proposes that it will instruct the MAC to issue a one-time lump sum payment to the hospital in the amount calculated using the proposed repayment formula described above.

Beneficiary Copayments

The proposed policy also states that affected 340B covered entity hospitals may not bill beneficiaries for coinsurance on remedy payments. CMS explains that because it plans to structure the repayment remedy as a lump sum payment, it proposes to account for beneficiary cost-sharing within the one-time lump sum payment to affected hospitals. CMS asserts that this adjustment is necessary due to the unique circumstances of the repayment and "to ensure equitable payments."

Prospective Offset for Higher Payments for Non-Drug Items and Services from CY 2018-2022

In the final part of the proposed remedy, CMS emphasizes the need to maintain budget neutrality as required under federal policy. Part of the 340B policy for CY 2018-2022 was an increase in payments for non-drug items and services. CMS claims that hospitals were paid $7.8 billion more for non-drug items and services during CY 2018-2022 than they would have been paid in the absence of the 340B payment policy. CMS asserts that to maintain budget neutrality it must implement an offset to maintain budget neutrality as if the 340B payment policy had never been in effect.

The proposed policy includes a budget neutrality adjustment by reducing future non-drug items and service payments. CMS proposes to adjust the OPPS conversion factor by minus 0.5 percent starting in CY 2025. CMS will continue this adjustment until the $7.8 billion amount is offset which is approximately 16 years.

To calculate the additional amount paid for non-drug items and services, CMS proposes to include status indicators to capture the non-drug items and services impacted by a change in the OPPS conversion factor. CMS proposes to begin the reduction in CY 2025 to allow time for CMS to finalize the appropriate methodology and then calculate and publish the payment rates in the CY 2025 OPPS/ASC proposed rule. CMS states this will allow adequate time for impacted parties to assess and prepare for the new payment rates.

New Providers

The proposed policy also addresses new Medicare providers. CMS states that any providers who did not enroll in Medicare until after January 1, 2018, did not fully benefit from the increased payment for non-drug items and services from CY 2018-2022. Therefore, under the policy new providers would be excluded from the prospective rate reduction.

Conclusion

CMS is soliciting public comments on the agency's proposed policy by September 5, 2023. Affected Medicare providers and 340B covered entities should submit comments regarding:

- the proposed calculation methodology for calculating the remedy payments owed to each covered entity hospital;
- the proposed interpretation of CMS statutory budget neutrality obligations, equitable payment authorities, and recoupment authority;
- the proposed definition of "new provider" and the proposal to exempt new providers from the annual adjustment; and
- the proposed annual percent reduction method for non-drug items and services.

Should you have any questions about this topic, please reach out to Janice M. Suchyta or another member of Baker Donelson's Health Law Team.