The Centers for Medicare & Medicaid Services (CMS) issued its annual proposed rule related to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems for 2023 (the HOPPS Proposed Rule) on July 26, 2022. Comments on the HOPPS Proposed Rule are due to CMS no later than September 13, 2022.

The HOPPS Proposed Rule can be found [here](#). This Alert summarizes proposed changes most relevant to pharmaceutical manufacturers and other participants in the pharmaceutical supply chain if finalized by CMS.

**Overall Payment Update to OPPS Providers**

- CMS has proposed increasing overall outpatient department payment rates by
2.7%, resulting in estimated payments to hospital outpatient departments for calendar year 2023 of approximately $86.2 billion, representing an increase of approximately $6.2 billion compared to estimated CY 2022 OPPS payments.

**Payment for Drugs, Biologicals, and Radiopharmaceuticals**

- The proposed packaging threshold (to establish a separate payment amount for certain drugs and biologicals) for calendar year 2023 will be set at $135 per day.

- For CY 2023, CMS proposes to continue the payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals, with the exception of drugs purchased at the 340B price, at Average Sales Price (ASP) plus 6 percent.

- Whenever WAC-based pricing is used for a drug or biological, such drug will be paid for at the current rate of WAC plus 3 percent.

- All biosimilar biological products will continue to be eligible for pass-through status, not just the first biosimilar biological for a reference product (guaranteeing separate reimbursement for a period of time regardless of whether under the packaging threshold).

- The HOPPS Proposed Rule also addresses CMS’ payment policy for drugs acquired under the 340B Program and the recent Supreme Court decision regarding those payment amounts. CMS states that “given the timing of the Supreme Court’s decision” in American Hospital Association v. Becerra, the agency was not able to incorporate the ruling of the decision into the calculations necessary to issue the Proposed Rule, and “for that reason alone,” CMS proposes to continue its current policy of paying ASP minus 22.5 percent for 340B-acquired drugs and biologicals. However, CMS stated that in light of the Supreme Court’s decision, the agency “fully anticipate[s] adopting, in the final rule, a policy of paying ASP [plus] 6 percent for 340B-acquired drugs and biologicals. This formal proposal is in accordance with the policy choices and calculations that CMS made in the months leading up to publication of this proposed rule before the Supreme Court issued its decision in American Hospital Association v. Becerra, No. 20–1114, 2022 WL 2135490 (June 15, 2022).”

As always, drug manufacturers and other participants in the pharmaceutical supply chain should take every opportunity to comment on policy and proposed rulemaking.

© 2022 ArentFox Schiff LLP

National Law Review, Volume XII, Number 215

**Source URL:** [https://www.natlawreview.com/article/cy-2023-proposed-hopps-rule-what-drug-manufacturers-need-to-know](https://www.natlawreview.com/article/cy-2023-proposed-hopps-rule-what-drug-manufacturers-need-to-know)