

Medicare 340B Payment Cut Déjà vu – Biden Administration Continues Trump Administration Part B Payment Reductions

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On Monday, July 19, 2021, the Centers for Medicare and Medicaid Services (CMS) released [the CY 2022 Medicare Hospital Outpatient Prospective Payment System \(OPPS\) Proposed Rule \(Proposed Rule\)](#). While the Proposed Rule contains a variety of proposed changes for CY 2022, *below are key updates affecting 340B Program covered entities and some initial recommended next steps as we continue to evaluate the proposal*. Comments are due September 17, 2021.

CMS confirmed it will continue its reimbursement cuts policy for certain 340B covered entities while it awaits a ruling from the Supreme Court in the ongoing litigation brought against HHS by the American Hospital Association (AHA). CMS also signaled that while certain 340B covered entities (rural sole community hospitals, children's hospitals, etc.) remain exempt from the reimbursement cuts, those covered entities should continue reporting the "TB" modifier and CMS may revisit the exemption in future rulemaking. Similar to last year, CMS also continued to reference the need for consistent and reliable payments for hospitals for the remainder of the Public Health Emergency (PHE), which could mean that payment changes can be expected following the end of the PHE.

Previously, HHS had been tasked with creating a remedy to make 340B entities whole after the D.C. District Court held the reimbursement cuts in 2018 and 2019 were unlawful. As part of its proposed solution, CMS issued its controversial 340B Drug Acquisition Cost Survey (Survey) to gather drug acquisition data from covered entities. CMS stated in this Proposed Rule that they had the authority to use the 2020 survey results to propose a new payment structure but believed the current payment policy is still appropriate, especially with the ongoing PHE. CMS continues to signal that its Survey data could influence future Part B / 340B drug payment proposals. Covered entities should act now and provide comments directed at the use of CMS's flawed Survey data. Namely, that the Survey was inappropriate, the method by which CMS sought to collect acquisition cost data was flawed, any reliance on the data would be misplaced given flaws, and results were inconclusive.

Notably, although the Biden administration has made staff changes within each agency, it appears that the same CMS personnel who were involved in last year's 340B payment section of the OPPS rule also participated in developing the Proposed Rule. While not dispositive of any issues, it's certainly noteworthy as many industry stakeholders question why the Biden Administration didn't

back down from payment cuts implemented under the prior administration.

Part B 340B Drug Payment Rates for Urban Hospitals

Ultimately, CMS did not propose any changes to payment for 340B drugs. The same payment policies implemented in 2018 and expanded upon in 2019 will continue throughout 2022 unless the Supreme Court rules in favor of covered entities or CMS alters course in its CY 2022 Final Rule. CMS will continue to pay covered entities ASP minus 22.5% for separately payable, non-pass through 340B drugs. Rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals would continue to be excepted from this reimbursement cut and would continue to be reimbursed at ASP plus 6%.

Update on Ongoing Litigation – American Hosp. Assoc. v. Becerra

In the latest on the case, an appeals court ruled in favor of HHS, stating that the Secretary had the authority to make the 340B reimbursement cuts. AHA appealed to the Supreme Court, which agreed to hear the case to determine if the Secretary has the statutory authority to make such substantial changes to Part B reimbursement for 340B drugs. Additionally, the Supreme Court requested HHS and AHA to address whether AHA's challenge is valid based on an OPPS statutory provision which purports to limit judicial review of certain agency determinations.

The Supreme Court is expected to hear the case during its next term, which begins in October.

Key takeaways for 340B Program Covered Entities:

- We recommend submitting comments to provide input regarding use of the Survey data and to outline the impact CMS's continued payment reductions have on covered entity communities. **Comments must be submitted by 5 p.m. EST on September 17, 2021.**
- Continue to report JG/TB 340B drug modifiers and budget for ASP minus 22.5% reimbursement for 340B drugs for CY 2022 until the Supreme Court rules on the case or CMS alters its course.
- Monitor billing/coding compliance relative to 340B drugs as failure to utilize appropriate modifiers can lead to overpayments and duplicate discounts (in the Medicaid context).
- Document files relative to the financial impact of the payment cuts for purposes of proving damages, if needed.

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