

340B Program Impacts in CMS Proposed Outpatient Rule

Multiple policies proposals within the Outpatient Prospective Payment System proposed rule will directly impact the 340B Program. Below highlights issues that covered entities should be aware of in the proposed rule. Click [here](#) for the CMS Fact Sheet, and [here](#) for the proposed rule.

Intent to Conduct Medicare OPPS Drugs Acquisition Cost Survey

Under the proposed rule, CMS announces the intent to conduct a survey by early CY 2026 on the acquisition costs for each separately payable drug acquired by **all hospitals** paid under the OPPS. CMS intends for the survey to be completed in time for the survey results to be used to inform policymaking beginning with the CY 2027 OPPS/ASC proposed rule. Refer to page 314 of the rule to view the notice.

This is directly from the Executive Order signed by the President in April of this year intended to lower drug prices. Within the EO, Section 5 requires HHS to conduct a survey of drug acquisition costs, this from the Supreme Court decision that stated this action must be met before CMS could pay lower prices for drugs to hospitals in its reversal of the Medicare 340B payment cuts. Click [here](#) for the EO, [here](#) for the fact sheet.

Site-Neutral Changes Would Impact 340B

CMS is proposing a policy of site neutral payments for drug administration services furnished in excepted off-campus PBDs, this will mirror the language in the House-passed bill - Lower Costs, More Transparency Act (H.R. 5378). Specifically, CMS is proposing to use the agency's authority under section 1833(t)(2)(F) of the Act to apply the Physician Fee Schedule equivalent payment rate for any HCPCS codes assigned to the drug administration ambulatory payment classifications (APCs) when provided at an off-campus PBD excepted from section 603 of the Bipartisan Budget Act of 2015. Refer to page 481 of the rule to review this proposal.

Section 11 of the April EO required CMS to move forward with the 2023 House-passed provision that would site-neutralize physician administered drugs at hospital outpatient departments to have payments at the same level as at private physician office. This will impact 340B savings as it would lower the payment amount from Medicare for off-campus, outpatient, physician-administered drugs.

Recoupment to Hospital Payments from 340B Cuts

Under the 340B Supreme Court decision on payments, CMS was required to recoup the increased payments paid to hospitals as a result of budget neutrality that increased other payments as a result of the cuts to 340B drug payments. Originally, CMS implemented a 0.5% reduction in payments until CY 2041. Under the proposed rule, CMS would increase the OPPS conversion factor reduction from 0.5% to 2% (beginning CY 2026) for non-drug items and services to recover \$7.8 billion in prior overpayments. Recovery would be completed by CY 2031. Refer to page 351 of the rule to review this proposal.