

HRSA Sends 340B Rebate Model Proposal to White House OMB for Review

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Federal health officials yesterday asked the White House's Office of Management and Budget (OMB) to review their latest proposed 340B rebate model pilot program—marking the first major action toward imposing 340B rebates since the public comments on the issue wrapped up in April.

OMB [reported](#) receiving a notice “regarding [the] 340B rebate model pilot program” from the Department of Health and Human Services (HHS) and Health Resources and Services Administration (HRSA) on May 27. The proposal—which is in the “prerule” stage—has yet to be published publicly, according to OMB's website.

The notice came just over a month after HRSA's April 20 [deadline](#) for stakeholder comments on a potential 340B rebate model and almost one year after HHS [submitted](#) its proposed guidance on its initial 340B rebate model for OMB review. HRSA previously [issued](#) a Feb. 25 information collection request, signaling the agency may pursue another rebate pilot for drugs selected for 2026 and 2027 Medicare negotiations.

The White House referred comment on the notice to OMB. OMB and HRSA did not immediately respond to 340B Report's request for comment.

Key Context

The American Hospital Association successfully sued to [block](#) the original 340B rebate pilot in December. Both a Maine federal district judge and a Boston federal appeals court found the pilot—which was set to take effect on Jan. 1—likely violated administrative law and did not adequately account for the potential financial harm to hospitals.

That pilot would have allowed manufacturers of the first 10 drugs selected for 2026 Medicare drug price negotiations to offer 340B pricing through post-purchase rebates rather than upfront discounts.

HRSA [issued](#) a request for information (RFI) on Feb. 13 to seek feedback on “whether HRSA should implement a rebate model under the 340B program and how best to operationalize any such rebate framework for stakeholders.”

HRSA's RFI appeared to be part of efforts to build a stronger legal and administrative foundation for any future rebate proposal, which would also likely face provider legal challenges.

HRSA received more than 5,500 comments on its RFI on a potential 340B rebate model, far exceeding the total it received last year on its now-halted rebate pilot proposal.

A drugmaker-funded patient group [submitted](#) around 1,001 duplicate comments supporting 340B rebates earlier in the submission process. However, most individual comments came from 340B providers, who argued that a 340B rebate model would create a significant administrative burden and harm their ability to serve vulnerable patients.

Manufacturers and aligned industry groups, meanwhile, continued to argue in their RFI comments that 340B rebates would improve program transparency and oversight.