

HRSA Sends White House Guidance To Cement Stance On 340B Rebate Models

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The Health Resources and Services Administration has sent a guidance document to the White House budget office that likely reveals its formal stance on the hot-button issue of whether drug makers can use a new rebate model to rein in 340B discounts -- coming as HRSA is poised to also tell a district court and stakeholders how it will proceed on the issue.

The DC district court ruled May 15 that drug makers need pre-approval from HRSA to replace the traditional upfront 340B drug discounts with after-the-fact rebates, but left it up to HRSA to unveil formal guidance laying out its detailed stance. HRSA sent 340B rebate guidance to the Office of Management and Budget on June 1, but the OMB website doesn't disclose what the guidance says.

The guidance likely lays out whether and under what circumstances drug companies can insist on rebate payments to covered entities for 340B drugs instead of traditional upfront discounts on medications.

On May 2, HHS sent a notice to the DC district court, which is overseeing suits by four drug companies and a drug discount management service challenging HRSA's warnings over their rebate payment models, that the department expected to be in a position to offer straightforward guidance on the issue to program stakeholders within 30 days.

"Large-scale implementation of rebate models to effectuate the 340B ceiling price would be a significant change for the 340B Program and its stakeholders. Because the implications are not straightforward, the Department of Health and Human Services continues to carefully evaluate its options alongside ongoing efforts to address 340B program integrity matters and keeping in mind the approaching effective date of certain Inflation Reduction Act requirements," HHS said in its May 2 notice to the court.

DC district court judge Dabney Friedrich eventually ruled on May 15 on the lawsuits from Eli Lilly, Bristol Myers Squibb, Sanofi, Novartis and Kalderos that HRSA is in the right for demanding that drug companies must adhere to the agency's pre-approval requirements before launching rebate payment models, saying the requirements did not exceed HRSA's authority under 340B statute. Friedrich also ruled that the court could not say whether HRSA permitting AIDS Drug Assistance Programs to use rebates in the 340B program without pre-approval while insisting that drug company proposals must be pre-approved was an arbitrary or capricious action.

The judge also ruled that because HRSA was still reviewing and had not yet approved any of the drug company plaintiffs' proposed rebate models, the court would not decide on whether HRSA had considered all

relevant factors, including pros or cons, regarding the models--and said the official decision on the rebate payment policy depends on HRSA.

Lobbies and trade associations representing 340B hospitals have been urging HRSA since the court's ruling to stand behind the warning letters the agency sent last year to drug companies seeking to transition from traditional 340B discounts to rebate payment policies that would affect certain covered entities.

In a May 9 letter to HHS, the American Hospital Association (AHA) said that while HHS was right to highlight how impactful a broader policy permitting rebate payments in the 340B program could be, HHS' May 2 notice to the court understated how much of a "significantly harmful" change the rebate models would be for hospitals and their most vulnerable patients.

AHA noted that implementing rebate payments would force hospitals to advance millions of dollars to drug companies despite already operating under lower margins than non-340B hospitals, and that hospitals might have to spend significant amounts of money to follow the rebate policies that could otherwise go towards patient care. Similar sentiments are shared by the trade associations 340B Health and America's Essential Hospitals, though 340B Health told *Inside Health Policy* it has not been briefed on the contents of the pending guidance at OMB

Since the May 15 ruling, BMS and Novartis have appealed Friedrich's decision, and the other two companies have until mid-July to appeal as well. A separate lawsuit filed by Johnson & Johnson is still waiting on a decision from the D.C. court as well, which could be made at any point, 340B Health Executive Director Maureen Testoni told reporters Tuesday (June 10).

Drug companies argue the proposed rebate policies, as well as separate 340B contract pharmacy restrictions several more companies have already established, are an effort to crack down on duplicate discounts and discount diversions, though 340B hospital advocates say such practices are not widespread.

The Pharmaceutical Research and Manufacturers of America alleges 340B hospitals have engaged in a \$66 billion markup program that allows hospitals to receive significant discounts on drugs and then charge patients full price or more and pocketing the difference, and continues to urges policymakers to consider reforms to the 340B program to combat this and other operational and oversight.

Several bills to reform 340B practices are pending on Capitol Hill.