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## Federal Judge Halts 340B Pilot Rebate Program

On Dec. 29, the U.S. District Court of Maine granted a preliminary injunction temporarily blocking implementation of a 340B pilot program HRSA intended to begin on Jan. 1.

As covered in a previous edition of *The Valued Voice*, HRSA's pilot would have allowed drug companies to move 10 drugs on the CMS Medicare Drug Price Negotiation Selected Drug list for 2026 to a rebate model in the 340B Drug Pricing Program, beginning Jan. 1. In a Sept. 8 comment letter, WHA expressed concerns that moving to a rebate model would significantly increase up-front costs and administrative burden for hospitals.

Given the concerns expressed by 340B covered entities, the AHA filed a lawsuit challenging that HRSA violated the Administrative Procedures Act and asked for the pilot to be blocked from starting due to the significant increased up-front costs and administrative burden.

U.S. District Judge Lance Walker agreed, writing in his decision, "The Agency's failure to abide basic requirements of the APA, Plaintiffs' irreparable injury should the program go into effect, as well as the balance of equities weighing in Plaintiffs favor, all counsel against permitting the Rebate Program to take flight on Jan. 1, 2026." The judge concluded HRSA acted "hastily" in its plans to launch the program, plans that included a "threadbare administrative record that likely fails to consider and reasonably explain the impact of a rebate model on 340B hospitals, who rely on upfront price concessions to stretch few resources as far as possible to serve rural and poor communities."

It is important to note that the decision is a preliminary injunction based on the likelihood that the AHA lawsuit may ultimately succeed, and not a final decision on the merits of the case. As such, the judge stated, "the anemic administrative record alone supports a conclusion that Plaintiffs have made a strong showing of likelihood of success." The judge also agreed there was likely to be irreparable injury should the pilot be allowed to go forward on Jan. 1, stating, "Plaintiffs' showing of economic impact and disruption to services is substantial and, paired with such a strong showing on the merits, sufficient to demonstrate irreparable injury." The judge cited HRSA's admission that it is "still reviewing public comments alleging an under-estimation of administrative costs" in his decision that HRSA appeared to be acting in a way that is arbitrary and capricious in failing to consider an important aspect of the problem.

WHA is continuing to follow this issue closely and will provide updates on the next steps in the process as they become available. Contact WHA Vice President of Federal Affairs and Advocacy Jon Hoelter with questions.

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### EDUCATION EVENTS

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