

August 8, 2025

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20852

Re: Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14998)

Dear Administrator Engels,

We, the undersigned associations, collectively represent the more than 2,000 hospitals that participate in the 340B Drug Pricing Program. On behalf of those members, we appreciate the opportunity to provide this initial comment on the Health Resources and Services Administration's (HRSA) notice of a 340B Rebate Model Pilot Program.

As the agency acknowledges, this pilot program marks a “fundamental[] shift [in] how the 340B Program has operated for over 30 years.” A change of this magnitude requires careful consideration by all stakeholders. To that end, the agency is seeking comments on its pilot program by September 8 and has asked drug manufacturers to submit rebate model plans by September 15. That timeline gives the agency *only one week* to consider any stakeholder feedback, make any necessary changes to its program, and communicate those changes to all 340B stakeholders, including the drug company applicants. With the fundamental changes a rebate model will impose on all 340B stakeholders, it is impossible for the agency to meaningfully consider, in just seven days, all the feedback it will surely receive. Moreover, drug companies have spent years developing and preparing for a rebate model, but the agency's current timeline would give 340B hospitals far less time to prepare.

We, therefore, respectfully ask the agency to extend the timeline for stakeholder comments, agency consideration, and manufacturer rebate plan submissions.

Specifically, we ask the agency to allow comments until September 15 and require manufacturer submissions by October 20, with any rebate model plan approvals made by November 3. This timeline would better allow stakeholders, including the 340B hospital field, to provide the agency with meaningful feedback, on the one hand, and would give the agency more time to consider any comments and make necessary changes to its rebate model pilot program, on the other hand.

We sincerely appreciate the agency's consideration of our request and look forward to working with all stakeholders on protecting the 340B program and the millions of patients who benefit from it.

Sincerely,

America's Essential Hospitals
American Hospital Association
American Society of Health-Systems Pharmacists
Association of American Medical Colleges
Catholic Health Association of the United States
Children's Hospital Association
340B Health