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Advancing Health in America

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September 30, 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: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-0111 - Extension

Dear Administrator Engels:

On behalf of our more than 2,000 member hospitals and health systems that participate in the 340B Drug Pricing Program, the American Hospital Association (AHA) appreciates the opportunity to comment on the Health Resources and Services Administration's (HRSA) information collection request (ICR) regarding the expected costs of its 340B Rebate Model Pilot Program. **The anticipated burdens on hospitals far exceed the agency's estimates, and the more than 1,000 comments that the agency recently received make clear that the pilot program will not be ready for implementation by the end of the year. At the very least, the agency should delay implementation until it can accurately account for these costs and solve the pilot's many operational challenges.**

The answer to your information request is plain: HRSA has vastly underestimated the burdens that this pilot program will impose on 340B hospitals. As it is, the agency has estimated more than 1.5 million hours of labor required per year to comply with the rebate model's data submission requirements. These numbers are extraordinary — especially for a pilot program limited to 10 drugs. But the burdens will far exceed even these estimates.

HRSA assumes that each covered entity will have to make 52 responses to the third-party platform of a drug company's choice and that each response will impose two hours of burden. Put another way, the agency assumes that hospitals will submit data *only once a week* and that each hospital will have to spend only two hours per week to

comply with this fundamentally different way of obtaining 340B discounts.[1] Reality dwarfs this estimate.

Our 340B hospital members have informed us that the rebate model pilot will require them to devote, on average, up to two full-time equivalents to manage the entire rebate model process.[2] Assuming each full-time employee works 40 hours/week, that would

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[1] Confusingly, HRSA makes this once-a-week-submission assumption even though nine different drug companies may be part of the pilot program. Our members anticipate making more submissions each week. That said, the agency may be assuming that hospitals will make a single submission to each company once a week, but our members inform us that this will take far longer than the assumed two hours.

[2] *See also* Letter from Martha Leclerc, Vice President, Corporate Contracting, Sanford Health to The Honorable Thomas J. Engels, Administrator, Health Resources and Services Administration, Re: Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14998) 1, 4-5 (Sept. 8, 2025) ("Sanford Health is the largest rural health system in the United States…. Rural providers especially often lack the staff and resources to manage these administrative requirements. *They may be forced to hire additional personnel or divert existing staff from patient care to manage the demands of multiple rebate systems. This shift would strain already limited resources and compromise the quality of care*." (emphasis added)); Letter from Binita Patel, Vice President, System Pharmacy Services, Memorial Hermann Health System to Chantelle Britton, Director, Office of Pharmacy Affairs, Health Resources and Services Administration, Re: 340B Rebate Model Pilot Program (HRSA-2025-14998) 2 (Sept. 8, 2025) ("Many hospitals anticipate the need for *new FTEs, development of new workflows, and additional IT resources* to meet these new requirements which would negatively impact the financial resources that Memorial Hermann will be able to devote to providing care to underserved populations." (emphasis in original and citing survey of 340B hospitals indicating that 98% of such hospitals reported having to allocate "additional personnel, by hiring new staff, redeploying existing staff and/or contracting external support, to manage contract pharmacy claim submissions")); Letter from Scott Leigh, 340B Manager & Cathy Simmons, 340B Executive Director, Government & External Affairs, United Point Health to Thomas J. Engels, Administrator, Health Resources and Services Administration, Re: HHS Docket No. HRSA-2025-14998 – 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program 6 (Sept. 8, 2025) ("Because covered entities are currently not required to collect and submit most of these data points to drug manufacturers, this will require extra resources, staffing, and compliance efforts. At UnityPoint Health, our 2026 calendar year budget had been set prior to this notice. Costs and cash flow disruption were not included in the budget. Due to the numerous outstanding implementation questions, it is difficult to forecast budget expenses for the Rebate Pilot or to estimate those expenses across 9 potential pilots. *Existing staff will be taxed to divert time and effort to the Rebate Pilot along with current 340B Program duties, and we will likely be forced to outsource some if not all Rebate Pilot compliance at additional expense. We question whether HRSA intends covered entities to use scarce federal resources to contract with third-party vendors, instead of providing patient services*."); Jenny Elhadary, Vice President, Clinical Services, Ann & Robert H. Lurie Children's Hospital of Chicago to Chantelle Britton, Director, Office of Pharmacy Affairs, HRSA, Re: HHS Docket No. HRSA–2025–14619 3 (Sept. 8, 2025) ("These requirements will necessitate hiring additional staff or reallocating existing personnel away from patient care to manage data submissions and compliance…. Some institutions estimate the need for at least one additional full-time equivalent (FTE) solely to manage data collection, formatting, submission, and rebate tracking."); Letter from John M. Carrigg, President & CEO, United Health Services Hospitals, Inc. to Chantelle Britton, Director, Office of Pharmacy Affairs, Health Resources and Services Administration, Re: HHS Docket No. HRSA–2025–14619 (Sept. 5, 2025) ("To comply with the Pilot's data submission and reporting requirements, UHS Hospitals anticipates adding four pharmacy FTEs and three revenue cycle FTE at an annual cost of $640,000 to ensure qualified staff with expertise in relevant laws, regulations, and electronic health record systems.").

result in nearly 4,160 hours across two full-time employees per year per hospital to comply with the rebate model.[3] With currently over 2,700 340B hospitals, that would amount to nearly 11.2 million burden hours — a far cry from the agency's estimates. Moreover, 340B hospitals indicated to us that the operational costs associated with the rebate model could range from $150,000 to over $500,000 per hospital, with costs increasing further if there are significant delays and denials with the rebate payments. Even a conservative estimate would yield over $400 million in annual costs for 340B hospitals to comply with the rebate model. And these costs don't include the millions of dollars 340B hospitals would be providing to drug companies as interest-free loans through the rebate model. They also do not include the nonmonetary burdens that patients and communities will suffer, and hospitals will then need to treat, because 340B covered entities will have fewer resources for health care services. **Spending these 340B dollars on administrative compliance with a pilot program, rather than using those funds to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," is manifestly counter to the program's purpose.[4]**

Ultimately, when calculated accurately, there is no way the benefits of this pilot program outweigh the burdens that will be inflicted on hospitals, health systems and other covered entities. As the AHA has noted, the pilot program does not even address the primary reason why the world's largest drug companies have clamored for the rebate model.[5] And if the only reason to conduct this pilot program is to facilitate compliance with the Inflation Reduction Act, there are cheaper, easier and fairer alternatives.[6] At best, this rebate model introduces a pointless administrative middleman into the process, adding the costs and burdens discussed above without making the 340B Program work any more efficiently or effectively for providers, patients or communities.

In fact, the agency's own estimates illustrate the lopsided burden imposed by the rebate model on covered entities when compared to drug companies. HRSA estimates 288

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[3] 40 hours/week x 2 FTEs x 52 weeks = 4,160 hours.

[4] *See* HRSA, 340B Drug Pricing Program, *at* https://www.hrsa.gov/opa; *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020), *rev'd sub nom.*, *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724 (2022) (quoting H.R. Rep. No. 102–384, pt. 2, at 12 (1992)).

[5] Letter from Chad Golder, General Counsel & Secretary, American Hospital Association to The Honorable Thomas J. Engels, Administrator, Health Resources and Services Administration, Re: Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14998) 9 (Aug. 27, 2025), at https://www.aha.org/system/files/media/file/2025/08/aha-comments-to-hrsa-on-proposed-340b-rebate-model-pilot-program-letter-8-27-2025.pdf ("[D]rug companies claim rebate models are necessary to reduce the incidence of statutory violations against diversion and duplicate discounts.12 But the pilot program expressly disclaims any effort to promote this goal. The Notice specifically forbids drug companies from denying rebates on the basis of their subjective allegations of noncompliance.").

[6] *E.g.*, Letter from Advocate Health Hospital Presidents to Chantelle Britton, Director, Office of Pharmacy Affairs, Health Resources and Services Administration (Sept. 8, 2025), Re: Request for Public Comment - Application Process for the 3408 Rebate Model Pilot Program [HRSA-2025-14619) (Sept. 2, 2025) 3 ("In short, the financial and administrative consequences of shifting to a rebate model far outweigh any benefits such a model may have for addressing '340B and Maximum Fair Price (MFP) deduplication.'").

hours of annualized burden on drug companies, while estimating over *5,000 times* the amount of annualized burden hours on 340B covered entities. This is particularly unfair because the rebate model is voluntary for drug companies, but mandatory for 340B hospitals and other covered entities. Thus, without any legitimate reason to implement such a program — the price tag does not justify the pilot. This is among the many reasons why it should be abandoned altogether.

At the very least, the agency should delay the start of the pilot program. A delay will allow the agency to better analyze and weigh the extraordinary costs and burdens it did not accurately assess when proposing the pilot in the first place.[7] What's more, some (but not all) of these higher burdens will occur because of the lack of operational clarity in the pilot program. For example, the agency has permitted each drug company to establish its own rebate process, including its own IT platforms. As the AHA has previously explained, that could result in *nine* separate processes and platforms that hospitals would be required to comply with.

Respectfully, these and other identified problems cannot be solved by January 1, 2026. A delay will allow HRSA to address the many operational and administrative problems that the AHA and others identified in the more-than 1,200 comment letters the agency received on its pilot program notice.[8] **A few months is not**

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[7] It is blackletter administrative law that a regulation is arbitrary and capricious if the agency failed to consider an important aspect of the problem. That includes, of course, considering the costs and benefits associated with the regulation. And as part of that cost-benefit analysis, the agency must identify benefits that bear a rational relationship to the . . . costs imposed. *Chamber of Com. v. SEC*, 85 F.4th 760, 777 (5th Cir. 2023) (internal citation and quotation marks omitted). Regrettably, the failure to accurately calculate the costs and burdens on covered entities, coupled with the failure to appropriately weigh those burdens against the nonexistent benefits of the pilot program, means this program is unlawful. *See generally Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983) ("Normally, an agency rule would be arbitrary and capricious if the agency … entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.").

[8] *See, e.g.*, *id*. at 2-7; Letter from Todd A. Nova & T. James Junger to Chantelle Britton Director - Office of Pharmacy Affairs (HRSA), Re: HHS Docket No. HRSA-2025-14619; Application Process for the 340B Rebate Model Pilot Program (Sept. 8, 2025) (listing operational challenges and burdens); Letter from UNC Health to Thomas J. Engels, Administrator, Health Resources and Services Administration & Chantelle Britton, Director, Office of Pharmacy Affairs, Health Resources and Services Administration (Sept. 8, 2025) (same); Letter from Trisha A. Jordan, Chief Pharmacy Officer, to The Ohio State University Wexner Medical Center to Chantelle Britton, Director – Office of Pharmacy Affairs (HRSA), Re: Re: HHS Docket No. HRSA-2025-14619; Application Process for the 340B Rebate Model Pilot Program (Sept. 8, 2025) (Sep. 8, 2025) (same); Jeffrey Akers, Vice President of Pharmacy Services, University of Cincinnati Health to The Honorable Thomas J. Engels, Administrator, Health Resources and Services Administration, Re: Public Comment – Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14998) (Sept. 5, 2025) (same); Letter from Jim Coleman, President and Chief Executive Officer, Erlanger Health to HRSA ("The proposed rebate model will introduce additional implementation

enough time for HRSA to address all of the challenges associated with a new regime that will, as HRSA itself acknowledges, "fundamentally shift how the 340B program has operated for over 30 years." Having failed to consider the true costs that such an underdeveloped pilot program will have on hospitals and patients across the United States, the agency cannot afford to get it wrong. For this reason alone, the agency should abandon this pilot program. **But if the agency is intent on moving forward, it should at a minimum take the time to get it right. Delaying the pilot program by one year or more will accomplish that goal**.[9]

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issues that are not yet sufficiently accounted for in the pilot design. Specifically, covered entities are already having to add additional staffing and resources to pull data, upload submission files, and follow rebate tracking. The introduction of these new workflows will require significant resources to navigate these new systems.").

[9] *See also* Jason McCarthy, Senior Vice President, Clinical Shared Services, Chief Pharmacy Officer, Corewell Health to The Honorable Thomas J. Engels, Administrator, Health Resources and Services Administration, Re: Application Process for the 340B Rebate Model Pilot Program (HRSA2025- 14998) (Sept. 8, 2025) ("It is difficult to comprehend how HRSA will be able to review comments on this demonstration, make corrections to potential design flaws, and ensure that this demonstration is conducted fairly for covered entities, drug makers, and even HRSA within this compressed timeframe. *We would suggest that HRSA at least delay the start of the demonstration to address these concerns*." (emphasis added)); Letter from Jennifer Rodriguez, Senior Vice President, Chief Pharmacy Officer, University Health to Health Resources and Services Administration, Re: 340B Rebate Model Pilot Program 1 ("[T]he implementation of the new IT platform for claim-level data submission imposes additional administrative burdens on the CE and raises privacy concerns associated with manufacturer platforms. *The short timeline for comments and plan implementation is inadequate to effectively address operational and IT challenges, as well as legal and privacy issues*. We would be required to establish the necessary interfaces for data transmission and allocate resources to managing denials and reconciling rebate payments, rather than prioritizing care for our most vulnerable patients." (emphasis added)); Mark L. Hayes, Senior Vice President, Policy & Advocacy, Ascension to The Honorable Thomas J. Engels, Administrator, Health Resources and Services Administration, Re: 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program (Sept. 8, 2025) ("Covered entities may need to renegotiate contracts with software vendors and third-party administrators to meet new requirements—negotiations that alone could exceed 60 days. A longer window is necessary to allow stakeholders to adequately assess and respond to operational, legal, and financial implications.… Additionally, the platform may require review by each covered entity's IT security department—a process that can be time-intensive and may necessitate software customization; these operational considerations must be incorporated into implementation timelines and planning.… HRSA should consider the operational burden on covered entities, including whether new technology or software development will be required to extract and report these fields for each claim. Building such functionality may require significant time and financial investment, which should be factored into program design, implementation timelines, and any compliance expectations."); Letter from Rachel Tanner, M.Jur., System Vice President, Regulatory Affairs, CommonSpirit to Thomas J. Engels, Administrator, Health Resources and Services Administration, Re: 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program 5 (Sept. 8, 2025) ("Giving notice of less than three months before implementation of such significant operational changes is not sufficient for covered entities to implement the infrastructure and staff needed to support the data submissions required to run these models and report the requested data.… [S]hould the Agency continue to pursue this pilot program the Agency must push back the application deadline and effective date to give covered entities and manufacturers ample time to implement."); Letter from Kate McCale, Vice President, Compliance and Regulatory Affairs, Hospital and Healthsystem Association of

We appreciate your consideration of these issues and would welcome a discussion at your earliest convenience.

Sincerely,

/s/

Chad Golder
General Counsel & Secretary

Pennsylvania to Thomas J. Engels, Administrator, Health Resources & Services Administration, Re: Notice 2025-14998 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program at 3 (Sept. 8, 2025) (**"The agency needs to extend the implementation timeline for at least one year to give manufacturers and covered entities enough time to put strong systems in place to meet the pilot program requirements."** (emphasis in original)); Letter from Alan Morgan Chief Executive Officer National Rural Health Association to Tom Engels Administrator Health Resources and Services Administration, Re: 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program 3 (Sept. 8, 2025) ("Implementing rebate programs beginning January 1st will put an immense burden on rural covered entities. HRSA should delay the start date until June 1, 2026, to give covered entities more adequate time to prepare.").