Illinois Health and Hospital Association

September 2, 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 20857

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

Dear Administrator Engels:

On behalf of our more than 200 hospitals and nearly 40 health systems, the Illinois Health and Hospital Association (IHA) appreciates the opportunity to provide comments on the Health Resources and Services Administration's (HRSA) 340B Rebate Model Pilot Program. We appreciate that HRSA is choosing to test a limited 340B rebate program (ten drugs) via a pilot rather than an all-drug, program-wide permanent change that would fundamentally shift the operations of a very successful 30-year program that providers and patients rely on to support access to medications and services.

Hospitals are not just healthcare providers. They are powerful economic drivers for their communities and for Illinois, infusing $117.7 billion annually into state and local economies. They offer good-paying jobs for working families; create jobs in other sectors; and purchase goods and services in their communities. This is especially true for 340B hospitals, which meet rigorous federal standards to participate in the 340B program. 340B hospitals are not only serving a disproportionate share of low-income patients, but they are often located in communities that rely on them for job creation, economic development, and neighborhood revitalization.

There are over 100 340B hospitals in Illinois serving countless low-income, underinsured, Medicaid-enrolled, and uninsured patients across the state. These hospitals are one part of a precariously funded healthcare safety net, ensuring all Illinoisans have access to high quality health services that support the needs of the communities they serve. Illinois' 340B hospitals provided a total of 1.46 million inpatient Medicaid days last year while operating on thin to negative margins. 340B hospitals use program savings to reduce patient out-of-pocket costs on high-cost specialty medications, operate health clinics in rural areas that have limited access to healthcare providers, and offer free healthcare services such as screenings and physicals to their communities.

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Given the critical role 340B hospitals play in the healthcare of Illinois, we are very concerned with any 340B rebate model, including the proposed 340B Rebate Model Pilot Program, as these models significantly depart from the 340B reimbursement process that has been in place for decades. Under a thin guise of compliance concerns, rebate models have been promoted by pharmaceutical companies as a means to reduce or eliminate the discounts they are required to offer. **Notwithstanding our appreciation of the limited nature of the 340B Rebate Model Pilot Program, its proposal casts a long, ominous shadow as it portends the possibility of expansion. We are very concerned that the pilot was conceived without input from hospitals, which are essentially required to participate should the drug companies they work with elect to participate. Given the lack of collaboration with 340B hospitals, we offer the following comments to strengthen the pilot program.**

The pilot program appears to impede Congressional intent for this program: to allow providers treating a disproportionate share of low-income patients the ability to stretch scarce federal resources and expand access to healthcare services. By implementing a rebate program rather than providing upfront savings, hospitals primarily serving patients enrolled in under-reimbursed government programs will be purchasing medications at a much higher cost. This has consequences.

Under a rebate program, a 340B hospital is forced to purchase 340B drugs with no guarantee that they will receive the differential between the wholesale acquisition cost and the 340B ceiling price as defined in section 340B(a)(1) of the Public Health Service Act (PHSA). **Simply put, participating in the 340B program that depends on rebates may cost eligible hospitals more than they realize or more than they are willing to risk, resulting in service closures or worse, hospital closures.**

As HRSA moves forward with the 340B Rebate Model Pilot Program, the agency must ensure drug companies participate in good faith by establishing strict enforcement guidelines. While the Notice stipulates that a drug company's rebate model application will be revoked if they are non-compliant with pilot program requirements, this language does not go far enough to penalize drug companies, particularly considering the critical financial implications this rebate model has for 340B hospitals. **We urge HRSA to exercise its authority under (d)(1)(B)(vi) of the 340B statute and impose civil monetary penalties for each instance of non-compliance exhibited by a pharmaceutical manufacturer under this pilot.** Examples of noncompliance include improper rebate denial, delayed rebate payment, and failure to pay for hospital costs and administrative burdens associated with the pilot program.

Regarding the rebate payments, we appreciate the 10-day rebate window after the drug is dispensed. We encourage HRSA to implement a rigorous enforcement mechanism to ensure rebates are paid to 340B providers in the prescribed timeframe. Additionally, **the agency should require drug companies to pay interest should they fail to provide rebates within 10 days, as allowed under 42 U.S.C. 256(d)(1)(B)(ii)(II).** Even with this 10-day requirement in

place, countless 340B provider types, including some 340B hospitals, will experience cash flow concerns and have to make hard decisions about staffing and service lines. Drugs are ordered months before they are dispensed, meaning the 340B provider will be financially liable for the wholesale acquisition cost of the drug from the time the purchase is made until ten days after the drug is dispensed. Requiring manufacturers to pay interest when they violate these terms is one small step toward balancing the financial stakes of this program across providers and drug companies.

Relatedly, we have concerns about whether rebate requests apply to the drug unit or the full package size as we consider the provided guidance ambiguous. We are concerned that manufacturers will look for loopholes to avoid honoring rebates should the rebate be tied to dispensing the full package, as a slow-moving drug may involve final units being dispensed more than 45 days after the first units were dispensed. While we believe HRSA's intent would be for the rebate request to come in within 45 days of the full package being dispensed, we think specific and firm guidance on this point is warranted given all of the process changes involved in this pilot program. Any ambiguity gives pharmaceutical manufacturers the ability to make this decision that will surely introduce administrative burden to providers, counter to the requirement that manufacturers bear the cost of the 340B Rebate Model Pilot Program.

We are also concerned by the potential lack of uniformity in rebate processes across drug companies. In addition to differences in guidance interpretation and rebate payments by unit or package discussed above, there does not appear to be a uniform information technology (IT) platform for manufacturers and providers to use when submitting rebate requests. **HRSA should establish and manage a centralized platform for data submissions.**

While the *Federal Register* announcement states that pharmaceutical manufacturers should shoulder the full administrative cost, the inevitable differing rebate processes across manufacturers will create administrative costs for 340B providers as they learn and comply with various IT platforms and data submission processes. In fact, the ten drugs included in the rebate pilot involve nine different drug companies, meaning providers may be dealing with nine different rebate processes across nine different IT platforms. Responding to differing processes and IT platforms will in itself increase administrative burden and cost for providers. By creating a centralized data platform, HRSA will alleviate this burden.

Unfortunately, variation in data submission processes and IT platforms are just two additional administrative costs we see with the proposed pilot model. Other potential costs include legal costs when providers pursue appeals of denied rebates, additional staff to implement rebate processes, and increased payments to providers' 340B third-party administrators to manage data flows across multiple drug dispensing channels. **To truly ensure that "no additional administrative costs of running the rebate model are passed onto covered entities," HRSA should clarify that drug companies must reimburse all additional costs. This should be part of**

the drug company application, which HRSA should not approve unless it makes certain that the applicants are willing to bear *all of the costs* that 340B hospitals will incur.

HRSA should also develop and implement a rigorous oversight mechanism to ensure inappropriate rebate denials do not occur. While the *Federal Register* announcement provides guidance on allowed and non-allowed rebate denials, it does not provide information on how HRSA will oversee this process. We are particularly interested in how HRSA will oversee allowed rebate denials in situations where the manufacturer believes two covered entities are requesting the same rebate for the same claim. The Notice is silent on how HRSA will determine whether this did in fact occur, and we are unaware of evidence that supports claims from drug companies that duplicate discounts (or in this case, rebates) are occurring.

Additionally, we ask HRSA to develop oversight for disallowed rebate denials to ensure manufacturers are complying with these rules. Drug companies' profits improve when rebates are delayed or denied. **There is no incentive on the part of drug companies to work in good faith to resolve disputes with hospitals over the timeliness of rebate payments, and HRSA has not yet issued specific guidance on what it will look for when assessing "trends toward" failing to pay or when there is enough evidence to revoke a manufacturer's rebate model approval.** Even if such denials are eventually overturned, any unnecessary paperwork or delay in rebates will create further administrative burden and financial strain on 340B providers, who do not have a choice in terms of participation if it involves the included drugs.

Relatedly, while the notice states that 340B hospitals can raise concerns around rebate delays and denials with the Office of Pharmacy Affairs, it only provides a general email for providers to use when submitting a complaint. It may be that HRSA intends to use the current Administrative Dispute Resolution (ADR) process; unfortunately, in many cases it may be inappropriate for 340B providers to use the ADR process under this pilot program. While denied rebates are in fact overcharges, statutory limits could preclude ADR review of any issues related to administrative or logistical issues with the rebate model. Additionally, the ADR process can take up to one year to make a decision, leaving hospitals on the hook for large sums of money that they may not have the financial health to float for an extended period of time. **IHA strongly recommends that HRSA create a separate dispute process for the rebate pilot program and produce specific rebate-dispute guidance that includes timelines and specific points-of-contact to receive and follow-up on complaints.**

Finally, IHA believes HRSA should not only complete an assessment of the 340B Rebate Model Pilot Program outlined in the *Federal Register* announcement but also, in full transparency, provide that assessment to Congress. This is especially crucial before considering any decision to expand the 340B Rebate Model Pilot Program. Congress created the 340B program, and any fundamental change, such as a rebate program, should be considered not only by lawmakers but also be presented to the public through Notice and Comment rulemaking.

HRSA has not established clear metrics on what determines success under this pilot program. We ask HRSA to do so, and to consider assessing the pilot program for programmatic efficiency and effectiveness, including whether the change to the payment process impacts providers and their ability to purchase medications under the program, maintain service lines, continue investing in the health and wellbeing of their patients, and maintain their position as economic anchors for the communities they serve.

In conclusion, we ask HRSA to ensure it has rigorous oversight of the 340B Rebate Model Pilot Program, and the parties participating in it (both manufacturers and 340B providers) to ensure 340B rebates do not result in unanticipated consequences, including restricting the fundamental purpose of the 340B program. HRSA should ensure that current 340B providers are not forced to exit the program due to cash flow issues, especially in states like Illinois that require 340B participation if a hospital is eligible. It is imperative that 340B hospitals, serving as anchors of communities and backbones of the healthcare safety net, are not forced into a situation that results in service lines being cut, or worse, hospital closures.

Administrator Engels, thank you again for the opportunity to provide comments on this pilot program. Please send questions or comments to Cassie Yarbrough, Assistant Vice President of Health Policy and Finance, at cyarbrough@team-iha.org.

Sincerely,

A.J. Wilhelmi
President & CEO
Illinois Health and Hospital Association