Illinois Health and Hospital Association

April 18, 2026

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: HHS Docket No. HRSA-2026-03042

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 U.S. Dept. of Health and Human Services (HHS) Health Resources and Services Administration's (HRSA) 340B Rebate Model Pilot Program.

More than half of Illinois hospitals participate in the 340B program ("Illinois 340B hospitals") and recognize the importance of this longstanding federal program to the financial sustainability of our healthcare system. 340B was designed to financially support providers that serve a disproportionate number of uninsured, low-income, or government-insured patients and allow them to stretch scarce federal resources to offer more services and free or discounted medications, all without using taxpayer funds. Congress intentionally expanded the program under the Affordable Care Act, allowing additional types of hospitals to participate and impact even more Americans.

However, the 340B program is under attack by the pharmaceutical industry. Under a thin guise of compliance concerns, rebate models have been promoted by pharmaceutical companies to reduce or eliminate the upfront discounts they are required to offer and, until recently, have offered for over 30 years. 340B providers have depended on these upfront cost savings, supported by meticulous record keeping, to fulfil the intent of the program—implementing and sustaining the services and programs their communities need to live healthy, fulfilling lives.

HRSA's 340B Rebate Model Pilot Program casts a long, ominous shadow as it portends the possibility of expansion to other drugs and undercutting those providers it was designed to help. Permitting rebate programs, including HRSA's 340B Rebate Model Pilot Program, will upend the financial stability of Illinois 340B hospitals. Rebate programs are administratively burdensome, create cashflow problems that jeopardize hospital resources, give pharmaceutical companies outsized control over the entire program, and endanger service lines and programs dependent upon the longstanding operation of upfront discounts.

Given that hospitals are essentially required to participate in this rebate program, IHA is very concerned that the pilot was conceived without input from hospitals and offers the following comments.

Administrative Burden

Any rebate model will create substantial administrative burden for Illinois' 340B hospitals. While the administration has indicated it believes hospital compliance with a rebate model will take four hours of staff time per week, many Illinois 340B hospitals have said they will need to hire an entire full-time staff member to execute the rebate model.

Administrative costs include the start-up costs of transitioning to a rebate system, including creating and implementing new workflows, in addition to the expected ongoing claim submission work, data tracking, reconciliation activities, dispute resolution mechanisms, and additional vendor support. These administrative costs will be exacerbated if pharmaceutical companies

implement disparate, varying rebate processes (e.g., various IT platforms and data submission processes), requiring Illinois 340B hospitals to further invest resources into chasing the discount to which they are entitled.

Taken together, the ongoing costs of implementing and complying with a rebate program will substantially cut into the benefits Illinois 340B hospitals receive and their ability to offer more services and free and discounted medications, flying in the face of Congress' intent in designing this program.

Cash Flow

In addition to administrative costs, any rebate program requires Illinois 340B hospitals to purchase medications at a much higher cost rather than providing upfront savings. This has consequences.

Under a rebate program, an Illinois 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). While HRSA may assume rebates will come to providers before money has to go out the door, wholesale distributors generally ask for payment within weeks. The timeline does not work, and Illinois 340B hospitals, that are already operating on thin to negative margins, are unlikely to have the cash they need to make payments in time. In fact, many Illinois 340B hospitals are consistently operating with about 30 days cash on hand. A rebate model also incentivizes pharmaceutical companies to delay reimbursements, as they are effectively receiving interest-free loans, further placing stress on Illinois 340B hospitals' cash flow.

Participating in this rebate model costs more than the upfront price of the drug. Coupled with the costs of creating, implementing, and maintaining the rebate program, the lack of upfront discounts may be more costly than what our hospitals are willing to risk, resulting in service closures or worse, hospital closures.

Outsized Pharmaceutical Manufacturer Power

While HRSA stipulates that a pharmaceutical company's rebate model application will be revoked if they are non-compliant with its 340B Rebate Model Pilot Program requirements, this language does not go far enough, particularly considering the critical financial implications this rebate model has for Illinois 340B hospitals. The damage will already be done.

Given the administrative and financial ramifications of this rebate program, HRSA must ensure drug companies participate in good faith by establishing strict enforcement guidelines. We urge HRSA to exercise its authority under (d)(1)(B)(vi) of the 340B statute and impose civil monetary penalties against pharmaceutical companies for each instance of non-compliance including improper rebate denial, delayed rebate payment, and failure to pay for hospital costs and administrative burdens associated with chasing the discount they are entitled to.

Regarding the rebate payments, we encourage HRSA to implement a rigorous enforcement mechanism to ensure rebates are paid to 340B providers in a tightly prescribed timeframe. Additionally, the agency should require drug companies to pay interest should they fail to provide rebates within the timeframe, as allowed under 42 U.S.C. 256(d)(1)(B)(ii)(II).

Even with a 10-day rebate requirement in place, countless 340B provider types, including some 340B hospitals, will experience the cash flow concerns mentioned above 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.

HRSA should also develop and implement a rigorous oversight mechanism to ensure inappropriate rebate denials do not occur. While we have seen past 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. Thus far, HRSA is silent on how it will determine whether this did in fact occur, and we are unaware of evidence that supports claims from pharmaceutical companies that duplicate discounts (or in this case, rebates) are occurring.

Additionally, we ask HRSA to develop oversight for disallowed rebate denials to ensure pharmaceutical companies are

complying with these rules. There is no incentive on the part of pharmaceutical companies to work in good faith to resolve disputes with Illinois 340B hospitals over the timeliness of rebate payments considering pharmaceutical companies' profits will improve when rebates are delayed or denied. 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 pharmaceutical company'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 Illinois 340B hospitals who, again, do not have a choice in terms of participation if it involves the included drugs of a pharmaceutical company.

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. While HRSA has indicated that 340B hospitals can raise concerns around rebate delays and denials with the Office of Pharmacy Affairs, to our knowledge there is only 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 the 340B Rebate Model 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 issue a decision, leaving Illinois 340B hospitals on the hook for large sums of money that they may not have the financial health to float for an extended period.

Damage to Patients

Illinois' 340B hospitals use 340B savings to support a variety of service lines and programs, all of which are at risk if this rebate program is implemented, or worse, expanded. Specifically, Illinois 340B hospitals utilize savings to operate retail, specialty, and mail-order pharmacy services in south Chicagoland and rural communities. Others use the savings to fund medication assistance programs that have reduced hospital readmission rates among vulnerable patients and send patients home with their medications to increase adherence.

These are in addition to utilizing their 340B savings for infusion therapy clinics, mobile dental clinics, outpatient centers in underserved communities, trauma and violence recovery programs, cancer care access, and charity care and uncompensated services provided to patients each year. Clearly, the current program allows 340B hospitals to stretch federal resources, investing them in the services and programs their patients need. When the rebate program cuts into 340B savings, these are the services and programs that will be cut. Any rebate program will decrease access to healthcare and social services, resulting in higher overall healthcare system costs.

Program Assessment

Finally, IHA believes HRSA should not only complete an assessment of the 340B Rebate Model Pilot Program but also, in full transparency, provide that assessment to Congress. This is especially crucial before considering any decision to continue or 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 the 340B Rebate Model Pilot Program. We ask HRSA to do so, and to consider assessing it 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 where 340B participation is required if the hospital is eligible. It is imperative that Illinois 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.

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