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September 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)

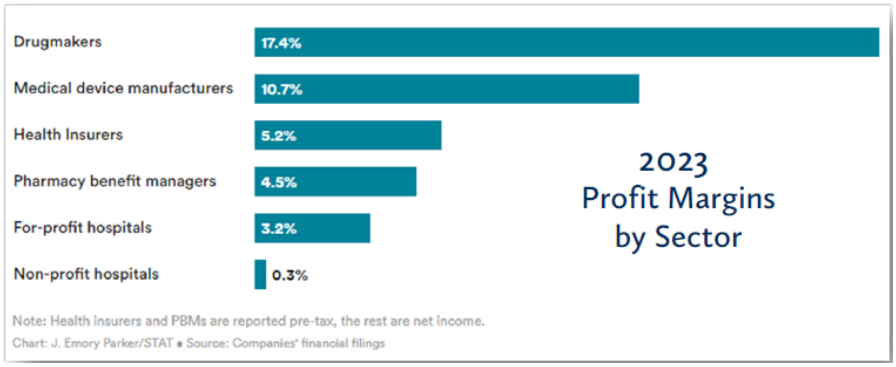
Dear Administrator Engels:

On behalf of our more than 150 member hospitals and integrated health systems, around half of which participate in the 340B Prescription Drug Pricing Program, the Wisconsin Hospital Association (WHA) appreciates the opportunity to provide comments on the Health Resources and Services Administration's (HRSA's) notice of the 340B Rebate Model Pilot Program.

WHA was established in 1920 and is a voluntary membership association. We are proud to say we represent all of Wisconsin's hospitals, including small Critical Access Hospitals, mid, and large-sized academic medical centers. We have hospitals in every part of the state—from very rural locations to larger, urban centers like Milwaukee. In addition, we count close to two dozen psychiatric, long-term acute care, rehabilitation and veterans' hospitals among our members.

The 340B program is extremely important to our members that qualify for it. Quite simply, many of our members' service lines would look drastically different if they lost their 340B discounts. The savings hospitals realize from these discounts truly stretches scarce federal resources – and would be the difference between maintaining or losing OB labor and delivery, behavioral health, or myriad other programs that cost hospitals significant dollars to operate, but that are nevertheless relied upon by the communities hospitals serve.

It is no stretch to say that the 340B program means more to Wisconsin hospitals, nearly 1/3 of which operated at a loss in WHA's 2023 fiscal survey, than it does to the drug companies that continue to make record profits even with the discounts they are required to provide under the 340B program. This point is illustrated by the adjoining chart prepared by STAT News. Despite the immense profits enjoyed by drug companies, 340B discounts account for only 3% of drug companies' global revenues.



WHA greatly appreciates HRSA's work to police adverse actions taken by drug companies, and has joined an amicus briefing in defense of HRSA, maintaining that HRSA, and not individual drug companies, has the authority to approve, deny or set other parameters regarding the lawful use of rebates in the 340B program. While WHA believes that ultimately this pilot will show the wisdom of HRSA operating 340B under a discount model for over three decades, nevertheless, WHA appreciates that HRSA has clearly put meaningful thought into creating strict parameters for this pilot, in line with their clear authority to do so.

Under HRSA's pilot program, 340B hospitals would be required to purchase the 10 drugs on the CMS Medicare Drug Price Negotiation Selected Drug list for 2026 at wholesale acquisition cost, submit certain data elements to drug companies, and receive a rebate within 10 calendar days of data being submitted. Drug companies would also have to apply for participation in the program by September 15, with approvals from HRSA by Oct. 15. Drug companies would be required to submit specific plans in 1,000 words or less detailing their use of a rebate model and would be required to ensure they are not passing along costs associated with data submission or other administrative costs to 340B hospitals.

Evaluating the Success of this Pilot

If HRSA moves forward with this pilot, it should keep at the forefront how it will define success. HRSA's stated goal of the pilot program is to "better understand the merits and shortcomings of the rebate model." WHA believes success should be evaluated based on whether or not the pilot advances the goals of the 340B program. According to Congressional Report language, and as HRSA notes on its website, "the **340B Program enables covered entities to stretch scarce federal resources** as far as possible, reaching more eligible patients and providing more comprehensive services." It is hard to imagine how moving 340B to a rebate model will advance that goal, for the following reasons.

1. **A rebate model is likely to add complexity.** For instance, moving to a rebate model will add to the complexity of the program, increase up-front costs for hospitals and other 340B covered entities (CEs), and put drug companies in control of deciding whether hospitals and other 340B CEs will ultimately receive the 340B discounts the program is designed to provide them. Such negative consequences for hospitals will also be felt by patients if hospitals and other CEs have to remove money-losing service lines to balance the result of their drug purchase costs increasing. ***Thus, if the pilot shows that moving to rebates does not help covered entities stretch scarce federal resources, then the pilot should be viewed as a failure and HRSA should not move forward with any future rebate models.***

2. **A rebate model will not benefit taxpayers.** It's also worth asking who benefits from moving the 340B program to a rebate model in the first place. As HRSA knows, the 340B program relies on no taxpayer money, but only discounts provided by drug companies. The only taxpayer money involved consists of the operational costs for HRSA to administer the program. Therefore, if moving to rebates adds complexity to the 340B program, it will not benefit taxpayers, but will actually be adding to the costs HRSA and others expend administering and complying with the program.

3. **Program integrity concerns among hospitals are not a sound reason for moving to a rebate model, since drug companies have far more program integrity violations than hospitals.** The actions by drug companies to sue HRSA to attempt to force them to move this program to a rebate program on their terms certainly suggests it is only in drug companies' interests to move the program to a rebate model. While they have claimed the reason for this is a need for program integrity to prevent duplicate discounts, the data shows otherwise.

   For instance, in 2022, 75% of drug companies that were audited by HRSA required repayment to 340B hospitals whereas only 28% of 340B hospital audits required repayments.[i] In fact, Between 2018 and 2022, 340B hospital audit data from HRSA shows duplicate discounts and diversion findings decreased

by a combined 62% and the amount of adverse audit findings were six times higher for drug companies than for 340B hospitals.[ii] If anything, the data shows a need to hold drug companies accountable for program integrity concerns rather than 340B hospitals.

Strengthening the Parameters Included in the Pilot

1. **Consequences for non-compliance.** WHA believes there must be real consequences for dug companies that do not comply with the parameters established in the pilot beyond simply revoking their rebate model application. HRSA should consider a mechanism that has more teeth, such as civil monetary penalties for each instance of non-compliance that is not corrected. Drug companies' actions in denying discounts HRSA requires at contract pharmacies show that they are eager and willing to flout HRSA policies if violating such policies does not lead to immediate consequences.

2. **Central platform for data submissions.** Complying with various aspects of the 340B program when there are constant changes to drug supply chains is already complex enough. Layering on further complexity with data submissions on the drug companies' terms will add even more complexity. For this reason, HRSA must come up with a standard platform that allows hospitals to seamlessly upload their data at no additional expense. Without a central data platform, hospitals could have 9 different IT platforms for the 9 different drug companies eligible to participate in this pilot. Hospitals are already dealing with a maze of portals for the myriad insurance company prior authorization requests they field; adding a new maze of portals for 340B would only add to this already significant regulatory burden hospitals bear.

3. **Do not allow rebates to become prior authorization for 340B.** HRSA must be extremely cautious not to give drug companies the ability to deny 340B discounts arbitrarily in the same way hospitals are already receiving denials for covered services under insurance company prior authorization policies. To avoid this, HRSA must create a dedicated process to resolve rebate disputes promptly with designated human points of contact and an expedited timeline for addressing complaints. HRSA should also require thorough and specific documentation for denials to allow covered entities to quickly address the reason for any denials.

Why A Rebate Model is Likely to Increase Costs and Complexity for Providers

As previously stated, WHA is concerned that moving 340B to a rebate model will harm hospitals by increasing their costs, something that will ultimately be detrimental to the patients and communities hospitals serve. A rebate model will increase the up-front costs hospitals must pay to acquire 340B drugs. Hospitals will be required to purchase drugs at the wholesale acquisition cost (WAC), the highest sale price for a drug and one that is not often paid due to the advent of group purchasing orders. For instance, three of these 10 prescription drugs list a WAC of thousands of dollars, with Imbruvica at nearly $15,000, Stelara at nearly $14,000, and Enbrel at over $7,000.[iii] Purchasing these 10 drugs at their WAC will require some hospitals to dip into their cash reserves and could be challenging for those hospitals with little cash reserves. Doing so could even impact a hospital's credit rating in a way that may have ripple effects on that hospital's financial situation. For instance, a credit downgrade for a hospital can lead to higher borrowing costs, thereby increasing costs for hospital construction projects and making it more challenging to increase access to care.

Not only will hospitals lose money by paying higher up-front costs, but without extremely tight parameters for timely repayment and swift resolution of any contested denials, hospitals are very likely to lose even more money by a rebate model that puts drug companies in charge of if and when hospitals will even get the 340B discount the law requires.

Lastly, it is hard to imagine that hospitals will not need to expend additional resources on compliance, data submissions, and appeals. The pilot allows drug companies to establish their own processes and IT platforms

that hospitals will need to adapt to. Running a 340B program already entails significant complexity as hospitals must constantly track changes in the thousands of prescription drugs they purchase as supply chains shift and alter package quantities, etc. Creating a whole new layer of 340B processes will add additional complexity.

Nearly one-third of Wisconsin hospitals already operated at a loss in 2023, a dynamic that has led to the closure of important service lines like inpatient behavioral health and labor and delivery. In some cases, these losses have culminated into closures, including two Eau Claire-area hospitals closing in 2024 after experiencing over $50 million in losses over the prior two years. With 340B discounts often being the difference between a Critical Access Hospital operating in the black versus the red, losing even a portion of these discounts can make a very real difference in a hospital's financial health.

In closing, WHA greatly appreciates HRSA's partnership in administering the 340B program. HRSA should be commended for designing a limited pilot that attempts to create strict parameters on how ten specified 340B drugs could move from an up-front discount model to a rebate model. Yet, HRSA can take additional steps to limit unintended consequences that could be detrimental for hospitals and the communities they serve, such as creating real consequences for drug-company non-compliance, establishing a central platform for data submissions to minimize additional bureaucratic work for hospitals, and creating strict policies that prevent the rebate process from functioning like health insurance prior authorization.

Above all, if the results of the pilot do not end up benefiting 340B covered entities in a way that advances the goals of the program – stretching scarce federal resources, then there is no reason to move the 340B program to a rebate model.

Sincerely,

Kyle O'Brien
President & CEO

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[i] https://www.aha.org/guidesreports/2025-06-16-more-drug-company-oversight-needed-maintain-compliance-340b-program-rules
[ii] Id.
[iii] https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf