The Hospital + Healthsystem Association of Pennsylvania

September 8, 2025

Thomas J. Engels
Administrator
Health Resources & Services Administration
5600 Fishers Lane
Rockville MD, 20857

Re: Notice 2025-14998 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program

Dear Administrator Engels:

On behalf of 235 member hospitals, health systems, and other health care organizations, The Hospital and Healthsystem Association of Pennsylvania (HAP), is grateful for the opportunity to comment on the Health Resources and Services Administration's (HRSA) 340B Rebate Model Pilot Program.

In Pennsylvania, 72 hospitals (in 30 counties) participate in the 340B program and serve our most vulnerable populations. About half are in rural areas—fifteen of which also offer critical labor and delivery services. Eighty (80) percent of the state's Critical Access Hospitals are part of this program. HAP is deeply concerned that guidance provided by HRSA gives drug manufacturers the opportunity to unilaterally make programmatic changes that will substantially impact the ability of these hospitals to remain afloat, jeopardize covered entities' ability to maintain 340B programs and significantly limit patient access to care.

Many 340B hospitals are the lifelines of their community, and the discounts they receive through the 340B program enable these organizations to maintain a broad array of services for their patients. However, these facilities are financially vulnerable. In Pennsylvania, 53 percent of the 340B hospitals operate with a negative margin. For hospitals, access to the savings the 340B program offers is the difference between a positive and a negative operating margin and a deciding factor when they consider what service lines to maintain. According to a report by the Commonwealth Fund, drugs purchased through the 340B program accounted for only 7 percent of the total U.S. Drug market.

Further chipping away at the financial viability of hospitals will have negative downstream effects on low-income and older patients. Pennsylvania's 340B hospitals use savings from drug discounts to reinvest in programs that enhance patient services and access to care, as well as provide free or reduced-price prescription drugs.

Pennsylvania's 340B hospitals are using the savings from the program to:

- Provide financial assistance to patients unable to afford their prescriptions.
- Provide clinical pharmacy services, such as disease management programs or medication therapy management.
- Fund other medical services, such as obstetrics, diabetes education, oncology services, and other ambulatory services.
- Establish additional outpatient clinics to improve access.
- Create new community outreach programs.
- Offer free vaccinations for vulnerable populations.

The abrupt transition from the current 340B upfront drug discount model to a claims-based rebate model for ten drugs that represent a significant portion of most programs is going to have serious financial and operational impacts on Pennsylvania's 340B hospitals and their ability to continue providing vital services to their communities. HAP strongly believes that the administration should consider an alternative program. Below are our concerns with the proposed pilot program.

Safeguards to Mitigate Adverse Impacts for Covered Entities

Delay the implementation timeline

The pilot design requires manufacturers to provide 60 days' notice before implementation of a rebate model. The proposed notice requirement is insufficient and does not give covered entities time to prepare for a transition of this magnitude. The timeline doesn't reflect the complexity of the programmatic and infrastructure changes required.

To transition to a claims-based rebate model with electronic data submission, covered entities will need to construct new internal programs that can compile the required data elements. They will need to make internal IT infrastructure changes to move the required information to manufacturers' platforms. Testing will be needed to ensure the integrity of manufacturer platforms and their ability to communicate with the technology and programs constructed by covered entities. Individually, each of these processes could take 60 days to put into place for just one rebate model and just one new IT platform.

It will not be possible to make this transition within the proposed timeline for multiple programs and manufacturers. The required processes listed above are further complicated by the lack of standardized requirements for rebate model programs and IT platforms. Each of the ten eligible manufacturers could all announce rebate models at

the same time, each of which could be slightly different, and each of which will use a different IT platform. Additionally, staff will need to be trained on how to use new internal programs and external IT platforms for the subset of drugs subject to the pilot rebate model while maintaining existing processes for 340B drugs outside of the rebate model pilot. Covered entities stand to lose rebates while they work through operational barriers while there are no penalties for manufacturers and no incentives to work with covered entities in good faith.

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.

Address implementation costs for providers

HRSA indicates that the transition to a rebate model should come at no additional cost to covered entities, but the guidance is not clear on how additional cost is being defined. The agency seems to limit cost considerations to those associated with data submission but also notes that no additional administrative costs of running the rebate model shall be passed on to covered entities. HAP would encourage HRSA to consider the costs associated with IT infrastructure changes, staff training, and additional staff requirements that will result from the increased programmatic reporting requirements. **If the agency moves forward with the pilot program, additional funding to cover the costs of implementation should be considered.**

Limit the initial financial impact by narrowing the scope of the pilot

The financial implications associated with buying drugs at the Wholesale Acquisition Cost (WAC) and assuming significant upfront financial risk cannot be understated. Covered entities have not had an adequate amount of time to financially prepare for the significant changes in drug-related expenses and will likely have negative margins (if they don't already) within months of the pilot program's implementation. For most programs, cash on hand will decrease by millions of dollars in the first 120 days of implementation.

Patients' access to medications will be directly impacted. Many programs will be unable to float the WAC price while they wait for rebates and will ultimately have to scale back their programs and the corresponding investments in their community. The scope of the rebate model needs to be narrowed during this trial period to protect 340B programs from financial losses that could lead to their demise. **If the agency moves forward with a pilot program, the rebate models should only apply to Medicare Part D plans and claims subject to the Inflation Reduction Act and not reach into**

the all-commercial payer space.

The framework laid out in the guidance does not correspond with the way patients access 340B drugs. According to the FAQs posted on the HRSA website, manufacturers are permitted to apply their rebates to physician and clinic administered drugs that do not have any Maximum Fair Price (MFP) payment due in 2026. At the same time, the notice only permits manufacturers to request data elements that only exist in the outpatient/retail pharmacy setting (such as RX number, Fill Number, BIN and PCN). These fields simply do not exist when a provider administers a medication as opposed to when a medication is dispensed through an outpatient/retail pharmacy setting. HAP is concerned that covered entities' inability to submit relevant data to the manufacturer will result in the payment period never starting, allowing the manufacturer to never honor the rebate. **Therefore, HAP is advocating that HRSA remove physician and clinic administered drugs from the pilot program.**

Finally, based on the concerns outlined above, the agency should not make any changes to the pilot program for at least two years and needs to clearly define testing parameters to determine the true impact of rebate models.

Incorporate additional protections for covered entities

Covered entities have expressed serious concerns regarding their ability to share the required data with drug manufacturers while maintaining compliance with HIPAA laws. Some of the required data elements are considered personal health information (PHI) and while disclosure of this information is not required by law, it will be required for covered entities to get their rebates—putting the financial interests of the covered entities at odds with the privacy interests of patients.

Covered entities also have no alternative to using the IT platform if they want to get their rebate. The guidance indicates that plans should ensure that the IT platform has mechanisms in place to protect patient identifying information in a manner consistent with HIPAA, covered entities will not be protected in the event of a data breach and covered entities will be subject to patient complaints for releasing their PHI. **HRSA should consider safe harbor provisions for the duration of the pilot program.**

Require manufacturers to standardize reporting and use a third-party IT platform

The guidance allows drug manufacturers to use their own IT platforms for data collection and lacks any guidance or protection for covered entities from unnecessary and harmful terms and conditions associated with using them. Pennsylvania's 340B

hospitals remain concerned that manufacturers will use these terms and conditions to adjudicate policy issues that have gone unresolved by Congress for several years by forcing covered entities to adopt manufacturers' "patient" definition and agree to restrictions on contract pharmacies. The power imbalance unfairly penalizes covered entities that will have to either agree to any terms or conditions of using the IT platforms or forgo 340B dollars. Similarly, manufacturers will easily be able to use the data for purposes outside the scope of the program with no recourse.

Drug manufacturers have already demonstrated in previous attempts to move to rebate models some of the harmful terms and conditions they intend to impose using the Beacon platform. The terms and conditions were non-negotiable and required covered entities to accept the following untenable terms:

- A perpetual, irrevocable data license.
- Third-party beneficiary enforcement rights in favor of manufacturers.
- Mandatory arbitration and class action waiver.
- Unilateral modification rights.
- Board monitoring and reporting authority.
- Only, a $100 limitation of liability in favor of the parent company (Berkeley Research Group/Second Sight).
- Illinois choice of law and venue.

Manufacturers should be required to use IT platforms that are agnostic of any manufacturer and the inputs for these platforms should be standardized. Or, at a minimum prejudicial terms such as those contemplated for manufacturer proposed rebate models should be prohibited. Instead, standard terms and conditions developed and approved by HHS should be implemented to avoid the inappropriate utilization/monetization of data and application of unrelated terms benefiting manufacturers and their third-party for-profit partners.

Put more guardrails in place around the Administrative Dispute Resolution process

HAP appreciates the safeguards HRSA attempted to put into place by prohibiting manufacturers from denying rebates based on 340B program non-compliance. However, we remain deeply concerned by the limited protections in place for covered entities should manufacturers begin to deny rebate requests broadly over de-duplication concerns (that a rebate was already provided for that claim) especially given that there is no guidance on how to determine which covered entity is entitled to a claim.

Once a rebate request is denied, covered entities must move through the administrative

dispute resolution process and fight for their rebate—a process that has not been effective in the surprise billing space. Pennsylvania 340B hospitals are deeply concerned that this process will be costly and burdensome and will further diminish 340B dollars—particularly since they will have to float the WAC price while the matter is resolved and, based on the current guidance, manufacturers have little to no incentive to participate in the Administrative Dispute Resolution (ADR) process.

A clear and fair rebate dispute resolution process must be established, including timelines, escalation procedures, and independent review mechanisms. Manufacturers must be required to specify the exact reasons for any rebate denials to ensure transparency and facilitate dispute resolution. HRSA must create penalties and implement safeguards that address manufacturer non-compliance by publicly stating that a manufacturer that fails to pay a rebate as requested by a covered entity will be considered to have overcharged the 340B covered entity and is therefore subject to civil monetary penalties.

Clarify and add flexibility to timelines

The timeline for repayment is unclear. The agency indicates that rebates need to be paid within 10 days but does not indicate when the ten-day period starts and, in some cases, defers to the manufacturers which will create multiple standards. For example, the agency indicates that the manufacturer should specify if rebates are paid at the package or at the unit level. This determination significantly changes the repayment period for covered entities, specifically those that may take extended periods of time to use all the units in a particular package.

Similarly, the guidance indicates that covered entities have 45 days to submit rebate requests. Covered entities report that 45 days is not enough time to reconcile patient visit data and identify any missed opportunities for rebates. Sometimes it takes weeks to find an issue and resolve it, particularly with new programs and processes. Covered entities are concerned they may not be able to solve all administrative errors causing unnecessary and significant financial damage—not to mention that most delays are often in the spirit of maintaining compliance with other program requirements. **HRSA needs to extend the timeframe to ensure adequate claim processing and reconciliation, particularly for complex or delayed transactions.**

Equip covered entities with the necessary tools to advocate on their own behalf

HAP would encourage the administration to consider the ramifications of recent court judgements, including *Astra, Inc. v. Santa Clara County (2011),* on the ability of

covered entities to negotiate on their own behalf. Covered entities cannot currently sue manufacturers over drug prices and have no recourse outside of the ADR process. Based on this guidance, drug manufacturers will shape the future of the 340B program and are positioned to dismantle it piece by piece resulting in hospital closures, service reductions and significant patient access issues—particularly for low-income and elderly patients.

To ensure transparency, HRSA, not manufacturers, should be responsible for providing covered entities with authoritative information regarding manufacturers' approved rebate models. HHS should also publish manufacturers' submissions on its website and publish manufacturer-specific FAQs to ensure that covered entities are not harmed by differing, changing interpretations of manufacturers' models that are not communicated to HHS, as occurs today with many drug manufacturers.

Thank you for your careful consideration of our comments on behalf of Pennsylvania's 340B hospitals.

Thank you,

Kate McCale, Vice President, Compliance and Regulatory Affairs