TEACHING HOSPITALS of TEXAS

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

Emailed via eRulemaking Portal: *https://www.regulations.gov*

HHS Docket No. HRSA-2025-14619 (90 FR 36163)

Dear Administrator Engels:

Thank you for the opportunity to provide comments on HHS Docket No. HRSA-2025-14619 (90 FR 36163) regarding a proposed program to test a 340B rebate model for certain prescription drugs and their manufacturers.

On behalf of the Teaching Hospitals of Texas, we are concerned that the proposed new rebate model will undermine the Congressional intent of the 340B program to "stretch scarce federal resources" for safety net providers. Contrary to that goal, conversion of the 340B program to a rebate model, even on a limited basis, will shift funding from safety net providers and the vulnerable patients they serve to manufacturers (many of which are based abroad), generating enormous and immediate cash injections to them, while injecting delays and denials into the 340B program. It also will enable manufacturers to avoid paying their fair share in exchange for participating in Medicaid and Medicare. It gives manufacturers hands-on access to the purse strings of a program intended to support safety net providers and their patients.
In addition, the rebate pilot as proposed fails to articulate the need for such a fundamental loss to CEs and patients and shift to manufacturers[i]. It also fails both to: include the oversight, parameters, and guardrails on drug companies needed to ensure a seamless and frictionless rebate of the 340B drug cost reductions (for which safety net providers have been eligible since 1992) and to provide the groundwork for a valid evaluation of pilot outcomes, thus undermining the rationale for the pilot.

We respectfully ask that HRSA withdraw and cancel the rebate program.

About Teaching Hospitals of Texas

The Teaching Hospitals of Texas represents a critical group of largely public and state hospitals. Our membership comprises about 4% of hospitals in Texas that anchor the

state's healthcare infrastructure, accounting for 40% of the state's GME training positions; 40% of the state's Level I trauma centers, and 44% of the nearly $8 billion in uninsured care costs incurred and reported by Texas hospitals. Despite being physically located in just 12 of the state's 254 counties, THOT members provide care to patients in *every one of Texas' 254 counties*, exemplifying the critical care that may not be available in other Texas urban and rural communities, including time-sensitive trauma care; specialty and subspecialty care; and best-in-class diagnostics and treatment options with some of the best clinicians in the state using the latest research-informed care practices. The 340B program is an essential part of the complex and fragile financing system that helps provide care for patients in our communities and across the state.

Key Concerns with the Proposed 340B Rebate Model:

While the lack of detail in the *Federal Register* notice makes it challenging to provide precise comments on operational concerns related to a 340B rebate model of payment, the concerns outlined below address the overall approach for a 340B rebate model as summarized in the notice.

1. The proposed rebate model will undermine Congressional intent for the long-established 340B prescription drug program by shifting funding and the balance of power to drug manufacturers. And as proposed the rebate model puts hospitals and other Covered Entities (CEs) in the unprecedented position of providing drug companies with interest-free loans in lieu of discount pricing.

The proposed rebate model will significantly and inappropriately shift funding and the balance of power to drug manufacturers providing them with immediate and significant reductions in expenses, increases in cash flow, and increased revenues generated from potentially hundreds of millions of dollars of increased cash on hand. CEs on the other hand will have immediate expense increases requiring them to increase budgets (or cut services), bear significant new cash flow costs, fund increased administration and oversight costs, and lose funding from likely manufacturer denials as CEs are forced to adopt a "pay and chase" approach to access the prescription drug price discounts Congress intended them to have. Rather than supporting CEs in stretching scarce federal resources as Congress intended, the financial shift under this proposed rebate model will <u>remove scarce resources</u> from CEs and significantly inhibit timely patient access to needed care and medicines – key elements in Making America Healthy Again.

The average <u>annual</u> float per 340B *disproportionate share (DSH) hospital if the entire 340B program shifts to rebate* — reflecting the difference between the higher cost of purchasing

340B drugs at wholesale acquisition cost and the 340B discount price — is estimated at $72.2 million *per DSH hospital*, according to 340B Health.

Even under this limited pilot as proposed, manufacturers will see a windfall from upfront cash on hand and CEs will lose access to those funds. The estimated financial impacts of the proposed rebate model (considering only the drugs including in this pilot) for just four THOT-member hospital systems would force them to provide a $265 million float to drug companies and carry $20 million in recurring monthly cash costs, tying up funds that should go directly to patient care.[1]

In broad business and economics terms, up-front discounts help consumers (340B CEs in this case) access the benefits of lower costs. Rebates, on the other hand, impose hurdles that provide a financial benefit only to those consumers that can successfully run the gauntlet of requirements set by the drug manufacturer providing the rebates. Rebates create a structural gap in the program, a forced delay of program benefits (discount) that also delays the funding required for patient care. Health care policy should seek to limit gaps in care; not create them, as this pilot would do.

This shift in financial advantage is precisely the reason why drug manufacturers have been and continue to seek to convert the 340B program from a straightforward, upfront discount to an after-the-fact rebate system; they want to reduce their costs which limits the benefit to CEs and their patients. Delays and gaps in accessing life-saving medications will occur, including, for example, for the over one in ten Americans with diabetes needing insulin and the 40% of Americans projected by the National Cancer Institute to be diagnosed in their lifetimes with cancer needing chemotherapy. To mitigate these care gaps, CEs will have to increase their budgets and allocate funds reserved to continually front load to manufacturers the value of the discounts.

This intentional delay of program benefits, resulting care gaps, and the transfer of funds from CEs intended to receive the full benefit of the program to drug companies are unprecedented.

Unlike upfront discounts, rebate paybacks are not guaranteed. They are subject to manufacturers' unilateral requirements, including timelines for data submission and manufacturer validation of the data and approval of the request. Rebate models that condition payment on a manufacturer's approval exercised at its sole discretion raise serious concerns about the potential for arbitrary or improper denials of rebate payments, or at the very least delays in owed, approved payment.

[1] See additional financial impact estimates on pages 9-10.

Even if every appropriate rebate request is approved, which is an extremely unlikely scenario, hospitals and other CEs will be required to advance drug companies hundreds of millions of dollars that are already budgeted for uncompensated care and services that traditionally operate at a loss (such as trauma care, psychiatry, and labor and delivery services).

Some CEs that also have 340B-related pricing discounts will lose those savings under the rebate model. And all CEs will face additional administration costs including for: IT systems (on required reconfigurations to prepare data for submission to as many as nine manufacturers potentially using different platforms with different unit measures (mL, milligram, packs, etc.), additional legal services, administrative reporting, compliance, rebate management, and dispute resolution[2] for implementation and ongoing program operation. And every time a new drug is added to the pilot, costs to CEs will increase.

We have provided financial loss estimates from several THOT members on page 9.

Manufacturers will claim that a rebate approach will not reduce the 340B benefit and that it simply delays the benefit of the program (i.e., the value of the lower price). But in reality, this proposal is like requiring insured patients to pay their full hospital bill upfront and then wait for their insurance company to send a rebate check weeks later. Even if everything goes smoothly and all claims are reimbursed on time, most families could not shoulder that upfront burden, and hospitals and other CEs cannot either.

2. The rebate model is voluntary for drug companies but mandatory for CEs, including hospitals.

HRSA consistently refers to the pilot as voluntary, yet it is mandatory for CEs. The shift in funding, increased costs, financial risks, and disruptions to patient care all fall to the CEs. Manufacturers, on the other hand, bear no mandatory risk: their participation is voluntary, so any risk is voluntarily sought. Not so for CEs, their patients and communities. In addition, the burden of proof and risks of pilot failure fall almost entirely on the CEs, not the prescription drug companies. If rebates are delayed and denied, if IT systems don't work, if drug company help lines aren't answered or responsive and if dispute resolution timelines

[2] The notice says manufacturers' pilot plans "…should include assurances that all costs for data submission through an Information Technology (IT) platform be borne by the manufacturer and no additional administrative costs of running the rebate model shall be passed onto the covered entities." It is unclear if this applies only to data submission, or to all the CEs' pilot implementation costs. We assume it means the former, leaving CEs with significant mandatory costs included those detailed above. Further, it is unclear how HRSA will assure that no costs are passed on and what recourse is available.

linger, the CEs will pay a price because the cash used for patient care will be with the manufacturers.

3. Requiring covered entities, including hospitals, to participate in the rebate model and to comply not only with federal regulations but also with each of the up to 9 drug company systems and requirements creates significant new administrative burdens and costs. By increasing administrative burdens and costs for CEs the pilot is misaligned with the Administration's objectives articulated in several executive orders to bring down prescription drug costs and reduce regulatory burden.

This rebate process likely will vary for each drug company, requiring additional administrative, IT, legal, and compliance investment from hospitals and other CEs, as well as modifying accounting practices to account for rebate "revenue," rather than discounted pricing, as well as additional resources to contest denied rebates claims and pursue remedies through HRSA's Administrative Resolution process. CEs will experience a significant increase in administrative costs because of this pilot.

Rebate programs, in this case "pay and chase" payments, are by design more administratively burdensome and costly to implement than the current upfront discount pricing. While there are only 10 drugs on the list for the pilot program, these equate to over 140 National Drug Codes (NDCs). This pilot will also disrupt CEs that currently only have 340B stock forcing them to utilize different purchasing models and updating contracts with wholesalers likely losing additional funding because these 340B-related discounts are no longer available.

Further, because the pilot does not mandate use of one platform and integrated reporting, administrative costs, overhead and complexities will be multiplied since CEs must work with up to nine manufacturers potentially requiring nine different systems and approaches for operating a rebate program and securing reduced-cost drugs.

4. The rebate model adds administrative burden and costs to state Medicaid programs.

Beyond the operational, compliance, and financial burdens created for CEs, state Medicaid programs will also have to take on administrative, technical, policy and procedural changes to accommodate the rebate model. The aggressive timelines and lack of operational details will be a challenge for state Medicaid programs, causing additional hurdles and delays for CEs to secure discounts to which they are entitled under federal law.

Additionally, since under the model, CEs are not guaranteed a rebate, it is unclear how coordination with Medicaid programs would work. CEs would need to wait until they know for sure whether they will receive a rebate before billing Medicaid and claiming a 340B

priced drug. Not only could CEs miss filing deadlines as a result, but also potentially could have delays receiving Medicaid payments.

5. Proposed timelines and lack of operational details make successful implementation impossible and further increase the costs to CEs.

The timelines provided in the notice are insufficient to ensure successful implementation of the rebate model. Implementation timelines and uncertainties further will increase costs to CEs.

Overall timelines are rushed and compromise both short- and long-term success for such a significant policy, operational and financial change in the 340B program. The proposal provides just 98 business days from federal notice to planned implementation: 29 business days for manufacturers to develop a plan (maximum 2 pages single spaced); 19 business days for OPA to review manufacturer's plans and make and post notification of selections; and 50 business days from plan selection to implementation.

Manufacturers are told they should allow 60 calendar days' notice to CEs and other stakeholders before implementation, including registration instructions for IT platforms. No details on manufacturer implementation notice content are provided. The program fails to provide a judicious, informed, methodical or thoughtful approach to the planned program implementation with related risks falling to CEs.

In their 50 days, CEs will need to review, plan, develop, finalize and implement workflows, IT, personnel, contracts with manufacturers and related adjacent contracts (e.g., IT, accounting, etc.), with as many as nine manufacturers using an unknown number of IT platforms. This 50-business day timeline assumes no time or process for engagement and Q&A with manufacturers on plans and related specifications.

While the 1000-word manufacturer plans should provide "a technical assistance/customer service component and ensure that opportunities to engage with the manufacturer in good faith regarding questions or concerns are made available to CEs through both the IT platform and a point of contact at the manufacturer" there are no related timelines, other requirements, or assurances.

6. The rebate program as proposed conflicts with HRSA's own stated goals of having a valid and methodical test and evaluation of rebates.

As proposed, there is insufficient time (best case 50 business days) to implement a change that HRSA acknowledges "…could fundamentally shift how the 340B Program has operated for over 30 years" and insufficient program and operational detail provided to ensure a valid and methodical test and evaluation of rebates.

The rebate model pilot will be unable to be properly evaluated because as outlined in the *Federal Register* notice, there is no stated definition of success or failure; there are no clear benchmarks for success/failure; and there is no evidence of how these benchmarks will be determined and who will determine them. HRSA itself seems unsure about the likely evaluation criteria as it has informed manufacturers that they "should agree to provide…periodic reports …[which] should detail data on purchases provided through rebates…and other information that *may evaluate the effectiveness* of the rebate model."

A 2-page single spaced plan is insufficient to provide the assurances and details needed for successful implementation, pilot and evaluation.

HRSA is also allowing manufacturers to propose new and different programs and criteria in their plans. This additional variability will add to CEs' implementation complexity and costs as well to the challenges for a valid evaluation.

Under the standard project constraints of time, quality, or cost, this impossibly short timeframe for such a critical program on which millions depend for access to care will result in higher costs and lower quality with patients and CEs bearing the brunt. Manufacturers on the other hand bare no mandatory risk: their participation is voluntary, so any risk is voluntarily sought.

Recommendations if HRSA Proceeds

In the event HRSA proceeds with the rebate program, we recommend:

- Delaying pilot implementation. As proposed, the 340B rebate model is scheduled to be implemented at the same time as another significant new pharmacy program: the Medicare Drug Price Negotiation Program. This dual implementation requires significant and costly program resources to implement particularly given the short notice for implementation of the proposed pilot. The dual implementation will also confound rebate model evaluation since there will be multiple variables changing at the same time.

  Further, as proposed, the rebate model is unlikely to be successful as there is little time to successfully create and implement such a fundamental change to the 340B program; there is insufficient program information (e.g., limited to the federal notice and manufacturers' 1000 word plans) and insufficient or lacking information on manufacturer compliance and enforcement; and insufficient detail to support a valid evaluation. HRSA should delay program implementation to support a successful pilot and evaluation, both of which are practically impossible as proposed.

- Making the pilot voluntary for both CEs and manufacturers.

- Requiring that all manufacturers use one data platform and one standard set of data elements.

- Establishing specific and well-established definitions and benchmarks of pilot success, evaluation criteria, and metrics, and other elements and processes needed to provide OPA with the "methodical and thoughtful approach to ensure a fair and transparent 340B rebate model process for all stakeholders involved."[3] In addition to focusing on manufacturer data as proposed, data-based impacts to CEs must also be included capturing their data on denial rates, payment timelines, administrative cost, cash flow impact from floating funds to manufacturers. Transparency from manufacturers, including external audit reviews of evaluation data also should be required. OPA should consider hiring an external, independent and issue – neutral evaluator for and well in advance of a pilot to design an appropriate evaluation methodology before it moves forward with a pilot.

- Implementing a voluntary pilot program with a dual track implementation: continue to require 340B discounts up front as they are today but allow voluntarily participating CEs and manufacturers to run a rebate model "sandbox" in parallel. In this voluntary parallel system, CEs will report on pilot drugs for rebate purposes to manufacturers. Manufacturers will report back on rebates they would provide while meeting timeliness and other requirements of the program. This parallel test will: identify and provide a basis for improving operational issues; provide data to accurately assess and evaluate the program; provide baseline data for manufacturer compliance, e.g., rebate denials; accuracy of rebates, etc. and other data elements that could be used for an evaluation of the proposed pilot and implementation year compliance.

  A parallel rebate model will also provide an improved basis to meet HRSA's stated goals for the program without shifting significant funding from CEs to manufacturers and without putting patient care at risk as the proposed pilot does. It will provide the basis for a bona fide evaluation and help identify likely cost impacts, funding shifts and operational challenges. It will put the risk of the program properly on the voluntary manufacturers which seek to take this risk: and not on the CEs and patients they serve.

Financial Impact to Texas' Teaching and Safety Net Hospitals

Four THOT-member hospital systems estimated the financial impacts of the proposed rebate model to their systems. **This rebate model pilot forces four hospitals collectively**

[3] Federal Register Announcement of Application Process for 340B Rebate Model; Supplementary Information section.

to carry a $265 million float and $20 million in recurring monthly cash costs, tying up funds that should go directly to patient care.

Best-Case Impacts (all rebates received within roughly one month):

- ***Total float*:** The gap between 340B discount pricing and non-discount (WAC) pricing for drugs ranged from $31 million to $91 million ($265 million combined float from just four hospital systems).
- ***Cash flow impact:*** The additional cash required to cover this float each month until rebates are received ranges from $2.3 million to $8 million, totaling $20 million. This is a recurring monthly drain that must be budgeted and therefore diverts resources away from patient care for as long as the rebate model is in place.

Anticipated Total Losses: (including denials, loss of investment income with funds held by manufacturers instead of hospitals and related losses)

- **Hospital system losses range from $5.3 million to $14.5 million totaling $38.8 million for just four public community hospital systems.**[4] This assumes a conservative 10 percent denial rate of rebate requests by drug companies, loss of associated 340B wholesaler discounts, business waste, cost of lost investment income, and at least $100,000 per year in new administrative costs.

Bottom line: A rebate model strains hospital resources and weakens the policy goal of stretching scarce federal resources to support patient access to care.

Thank you for considering our comments. Sincerely,

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Austin, TX 78701

[i] We recognize that one purpose of this proposed rebate pilot is to attempt to solve the problem of possible duplicate discounts that was created by Medicare negotiation pricing to ensure that covered entities do not receive both 340B pricing and a Maximum Fair Price (MFP) rebate. However, there are alternative approaches that could be used to achieve de-duplication that would not undermine the integrity of the 340B program or jeopardize the healthcare safety net. For example, some 340B leaders have suggested that drug manufacturers, covered entities, and payers could participate voluntarily in a neutral clearinghouse or claims data repository that could be designed to prevent duplicate discounts. The Center for Medicaid Services (CMS) previously solicited comments on establishing a Medicare Part D claims data repository to comply with requirements to exclude 340B from total Part D relatable units. CMS was considering this proposal specifically for inflationary drug penalty calculations, but it could be expanded and used to support deduplication of 340B and MFP rebates.

[4] The 10 percent denial estimate is likely understated given the potential for abuse in a "pay and chase" model. Likewise, the $100,000 in annual administrative costs is a conservative placeholder.