AMERICA'S ESSENTIAL HOSPITALS

December 1, 2025

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration (HRSA)
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20852

Re: Requests for Additional Implementation Guidance and Response to Critical Comments on 340B Rebate Model Pilot Program (340B Program Notice: Application Process for the 340B Rebate Model Pilot Program, Docket No. HRSA–2025–14998)

Dear Administrator Engels:

America's Essential Hospitals appreciates and supports the efforts of the Health Resources and Services Administration (HRSA) to oversee and protect the 340B Drug Pricing Program so that covered entities can continue their work to "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] In that vein, we submitted comments on Sept. 8, 2025, regarding the above-referenced notice creating the rebate pilot program. Our comments expressed significant concerns about upending a core element of the 340B program and exponentially increasing up-front drug costs for safety net providers across the country. Additionally, we identified critical issues that the agency must address to mitigate negative impact to the greatest extent possible and ensure access to critical discounts during the pilot period. We write today because many of those issues remain unaddressed despite the rapidly approaching start of the pilot. **We respectfully request a meeting at your earliest convenience to discuss these concerns and mitigate confusion among covered entities forced to participate in the pilot program.**

America's Essential Hospitals is the leading association and champion for hospitals dedicated to high-quality care for all, including those who face social and financial barriers to care. Since 1981, America's Essential Hospitals has advanced policies and programs that promote health and access to health care. We support our nearly 400 members with advocacy, policy development, research, education, and leadership development. Communities depend on essential hospitals for care across the continuum, health care workforce training, research, public health, and other services. Supported by Essential Hospitals Institute, the association's research and education arm, essential hospitals innovate and adapt to lead all of health care toward better outcomes and value.

[1] REP. 102-384(II), p. 12.

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We appreciate HRSA's steps to communicate details about the rebate pilot and its extension of the comment period prior to moving forward with the program. However, the current implementation approach—particularly the absence of publicly posted manufacturer plans and the lack of response to numerous questions raised during the comment process—raises substantial legal and operational concerns. While we still contend a rebate model is neither legal nor obligated under the 340B statute, we urge HRSA to take steps to alleviate the outstanding questions of essential hospital 340B participants.

Our members continue to have significant questions about the implementation and intent of the program. Given the importance of access to legally mandated ceiling prices for 340B covered entities, it is critical that HRSA ensure program integrity over the rebate pilot. The following points are necessary to ensure covered entities' rights are protected during the rebate pilot.

- It is vital that HRSA increase transparency around the rebate pilot program. **We urge HRSA to publicly post the submitted and approved manufacturer plans.**

- **HRSA must ensure an adequate process for reporting and resolving disputes over denials and any other inappropriate restriction of access to ceiling prices.** HRSA has a statutory duty to ensure compliance with the 340B statute, protect covered entities' access to ceiling prices, and prevent manufacturer overcharges (42 U.S.C. § 256b(d)(1)(B)(i)–(vi)).

- **HRSA must conduct oversight over implementation choices and changes by platform vendors** like Beacon Channel Management and manufacturers. We are concerned that manufacturers and vendors could make changes without notifying or seeking approval from HRSA. Such changes could counter HRSA's intent, be implemented without HRSA approval or notice to providers, and result in additional expense for providers. We are concerned by the independence with which manufacturers and their chosen information technology platform are implementing their proposed pilot. Under federal law, HRSA oversees the 340B program—not manufacturers, nor manufacturer-selected firms. Since the Oct. 30 notice from HRSA, Beacon has already amended responses on its FAQ page. Reliance on an FAQ page—particularly one hosted by an interested private party rather than a federal agency—is an inappropriate and unreliable means of communicating changes to a statutorily authorized program. Any changes to the 340B rebate pilot must be made and authorized by HRSA, not by manufacturers with a pecuniary interest in limiting the number of 340B discounts.

- We also fear that the initial 45-day claims submission window is insufficient to ensure all lawfully obligated 340B discounts are made available to covered entities, particularly during the initial transition period to the rebate model. **We urge HRSA to extend the 45-day window to 90 days during the initial pilot period while covered entities, IT vendors, and manufacturers learn how to navigate this new paradigm.**

Additionally, we are concerned that many outstanding questions must be considered before the rebate pilot commences. To that end, we have identified questions for HRSA's consideration that we believe must be addressed for covered entities to understand their legal obligations, protect their rights, and participate in the pilot without exposing themselves to financial or compliance risks (*see attached list*). HRSA and all 340B stakeholders will engage in significant

efforts to test the pilot and understand implications, but this testing can only yield meaningful insights if there are clear processes to define rules, collect information about issues, and engage in clear and meaningful efforts to address them. **We respectfully request a meeting to review critical questions raised by our members and work with HRSA to address them**.

Thank you for your consideration of this request, and we look forward to speaking with you at your earliest convenience. If you have questions about this meeting request or need more information, please contact Senior Vice President of Policy and Advocacy Beth Feldpush, DrPH, at bfeldpush@essentialhospitals.org or 202-585-0111.

Sincerely,

Jennifer DeCubellis
President and CEO

Questions for Requested Discussion
America's Essential Hospitals

A. *Notice*

Question: Does HRSA have any policy in place to communicate minor and major changes in the pilot program?

Under the Administrative Procedure Act (APA) and basic principles of program administration, government agencies must provide clear, authoritative notice of federal requirements. Since the first slate of rebate models were authorized on Oct. 30, covered entities have had to rely on manufacturers and the Beacon platform, rather than HRSA itself, for updates on program implementation.

HRSA's use of FAQ on its website to share program updates is helpful, but it is not the most effective method for sharing important details on a tectonic shift in the 340B program. For example, the current version of HRSA's FAQ states that the Office of Pharmacy Affairs (OPA) "will evaluate potential incorporation of certain purchase data" as the pilot progresses. If HRSA opts to require covered entities to begin submitting additional claims fields, how will such change be communicated to stakeholders? And should covered entities expect changes to be made in the middle of the initial pilot year?

Reliance on manufacturer-owned FAQs raises additional due process and transparency concerns, as well as questions about compliance with the rebate plan approved by HRSA. Many details are not necessarily addressed in the plans, and can have serious policy implications (e.g., the patient definition concern recently raised by manufacturer definitions of 340B ID). How is HRSA monitoring potential unilateral changes to rebate model implementation and how does it plan to ensure these changes comply with HRSA's obligations under the 340B statute? Further, if changes are warranted, how will these changes be communicated to covered entities?

B. *Oversight*

Question: Has HRSA validated the Beacon platform's rebate platform and methodology, including veracity of claims identification and protection of personal health information (PHI)? If so, what criteria did HRSA use?

As the agency designated in the 340B statute to house OPA, HRSA is obligated to monitor manufacturer compliance. To date, HRSA has not publicly communicated details regarding PHI protection standards of rebate platforms, like Beacon. If there is a statutorily permissible version of the 340B rebate pilot—which we still contend is not obligated or permissible under federal statute—any implicated information technology platform must meet the same program compliance standards as HRSA. IT platforms participating in the rebate pilot must conform to all legal requirements regarding receiving, holding, and transmitting any PHI.

C. *Claims Disputes*

Question: Will HRSA articulate the limited set of permissible grounds for manufacturer denials?

HRSA took critical steps in the Federal Register Notice by prohibiting manufacturers from denying 340B rebates based on compliance concerns with diversion or Medicaid duplicate discounts. However, HRSA has not provided an exclusive list of the grounds for which denials would be permitted. Before a majority of the plans go into effect on Jan. 1, HRSA should explicitly detail under what circumstances a manufacturer can or cannot deny a claim.

Question: Will HRSA specify standardized documentation requirements for claim denials and appeals to avoid inconsistent manufacturer-by-manufacturer processes?

We acknowledge that the Federal Register Notice requires that manufacturers provide a rationale and specific documentation for reasons claims are denied; however, since the manufacturers' plans are not public, it is unclear whether the documentation and level of detail will be consistent among manufacturers. HRSA should standardize the required documentation for denials and the process for disputing such denials.

In cases where a claim denial is being disputed, HRSA's FAQ direct covered entities to communicate first with the claims IT platform, next with the manufacturer, and only then should covered entities raise their concerns with HRSA. But the manufacturers' letters to covered entities state differing processes that covered entities must take to rectify denials due to missing fields and multiple covered entities submitting the same claim. For example, in the case of multiple covered entities submitting the same claim, one manufacturer stated that the covered entities must resolve that issue with each other, while another manufacturer stated that it will only recognize the first submitted claim. The process for disputing the same types of denials should be standardized across manufacturers.

Additionally, if a covered entity cannot resolve an issue with the IT platform or manufacturer, its only other option is to detail its concern in a note to *HRSA's generic 340B email address*. Covered entities may face concerns with a high number of claims, clogging the agency's inbox and putting administrative strain on both parties. HRSA has also not identified what documentation should be provided in such an email to ensure swift resolution. We urge HRSA to publish a dedicated email inbox and phone number for covered entities to contact HRSA for issues pertaining to the pilot program and ensure a prompt response.

To reduce administrative burden for both covered entities and HRSA, covered entities should receive a clear, standardized process for resolving claims disputes.

Question: How will disputes over payment amounts—not applicability—be handled?

The rebate pilot dictates that the size of the rebate will be calculated as a wholesale acquisition cost, minus the 340B ceiling price *on the date of dispensing the product* (rather than on the date of purchase). We have grave concerns that this complicates 340B implementation and has the potential to functionally increase drug costs for 340B covered entities above what entities would pay absent the rebate model.

We are also concerned that transaction processing can occur on a different date than when the drug was dispensed by pharmacy; this could create a price discrepancy between the 340B price on the service date required for claims submission and the date the drug was dispensed. In an instance where a manufacturer has paid out a claim, but at a lower rate than due, covered entities need an administrative path for correction.

D. Enforcement

Question: For purposes of removing noncompliant manufacturers from the program, how will HRSA identify when a manufacturer "trends toward. . .not paying rebates within 10 days of data submissions," and how will HRSA communicate that status to manufacturers?

In HRSA's published FAQ, the agency appropriately determines that manufacturers that do not comply with program requirements may be removed from the pilot program. Specifically, HRSA reserves the right to remove a manufacturer from the program if the agency observes that a manufacturer trends toward not paying rebates within 10 days of data submissions. As we expressed in our previous comment letter, we remain deeply concerned with this ambiguous standard. **HRSA should instead require manufacturers to abide by the 10-day window**. However, if the agency is adamant on keeping the aforementioned "trends toward" standard, we are concerned by the lack of detail in how HRSA will identify and address consistent failures to abide by the rules of the pilot. Furthermore, the failure to establish clear parameters justifying removal from the program poses a future litigation risk for HRSA in the event it removes a manufacturer from the program.

Question: How will HRSA observe when manufacturers are "unable to timely resolve rebate reimbursement issues," and how will HRSA communicate that status to manufacturers?

HRSA's FAQ preserve the agency's ability to remove manufacturers from the program if they "are unable to timely resolve reimbursement issues." We are concerned with the lack of detail regarding how HRSA will measure whether a manufacturer is timely resolving reimbursement issues. Not only does the failure to provide a standard give manufacturers unnecessary leeway, as stated above, the failure to establish clear parameters justifying removal from the program poses a future litigation risk for HRSA.

Question: What additional measures will HRSA take to penalize noncompliance/encourage compliance short of the significant step of removing a manufacturer from the program? Will a manufacturer be assessed a civil monetary penalty (CMP) if it substantially delays a rebate for an eligible 340B sale? What if the manufacturer ultimately refuses to provide a rebate on an eligible 340 sale?

Under federal law, HRSA holds the statutory duty to ensure accurate ceiling-price calculations, and to ensure that obligated discounts are provided to 340B covered entities. Any manufacturer participating in the 340B program that "knowingly and intentionally charges a covered entity more than the ceiling price, as defined in § 10.10, for a covered outpatient drug, may be subject to a civil monetary penalty not to exceed $5,000 for each instance of overcharging."[2]

In an instance where an obligated rebate claim is left unpaid, and a covered entity is unable to realize a 340B discount, a manufacturer has definitionally charged a covered entity more than the ceiling price. In an instance where prompt access to statutorily obligated 340B discounts has been denied due to manufacturer malfeasance, HRSA should levy CMPs on the responsible

[2] 42 CFR 10.10

party. HRSA should clearly articulate the specific circumstances under which CMPs may be levied and how they will be enforced.

E. Data Protection

Question: How will HRSA ensure that data provided to manufacturers or the Beacon platform will not be used for purposes outside the rebate pilot, including targeting of contract pharmacies or audits?

We find HRSA's decision to expand the slate of permissible claims fields—beyond the initial pharmacy claims fields outlined in the original notice—deeply troubling. Manufacturers have a documented history of misusing data to restrict covered entity access. HRSA has a duty to safeguard PHI and to maintain program integrity. The addition of subsequent claims fields increases compliance burdens and provides an opportunity for manufacturers to misuse data for purposes beyond the scope of the rebate pilot.

Moreover, the Beacon platform's own FAQ indicate that data created in the rebate model is integrated with the Beacon MFP platform to assist with MFP duplication. Even more troublesome in the Beacon FAQ is the suggestion that the 340B rebate data will be used beyond the stated purpose of the pilot to identify instances of duplication in Medicare, Medicaid, and commercial channels and ensure that the "corresponding rebate in the other channel is reduced or rejected."

F. Continuation/Expansion of Pilot

Question: How is HRSA evaluating the rebate pilot, and what measures will it use to determine if the pilot should be continued or even expanded in 2027? Will HRSA commit to a formal notice-and-comment period prior to making any substantive changes to the 340B Rebate Program, including expansion or extension of the pilot?

HRSA's Federal Register Notice states that the pilot would run for a minimum term of one calendar year. Further, HRSA states OPA shall use its experience implementing this pilot "to better understand the merits and shortcomings of the rebate model from stakeholders' perspective, and to inform OPA consideration of any future 340B rebate models." At this time, HRSA has indicated its intent to gather feedback from stakeholders but has not formalized any processes to do so.

While we remain strongly opposed to the initial implementation of the pilot, HRSA must provide clear details for how it intends to evaluate the rebate pilot and gather feedback from stakeholders. Providing clear measures will allow covered entities to better document and detail their experience in ways that will be useful to understand the pilot's successes and/or shortcomings.

G. Additional Concerns

Question: If the Beacon platform or a subsequently implicated IT platform experiences downtime or a data breach, what is the fallback process for covered entities?

Essential hospitals operate with significantly lower financial margins than peer hospitals, including even other 340B hospitals. According to our analysis of Medicare Cost Reports, in 2023 essential hospitals survived with an operating margin of -7%, more than three times lower than other acute-care hospitals.[3] This financial reality means essential hospitals often have extremely limited cash on hand. The rebate pilot stands to already disrupt this fragile equilibrium, but instances where discount access is further delayed could prove disastrous for essential hospitals.

Question: Is HRSA coordinating with state Medicaid agencies to establish a process to reverse or correct 340B claims modifiers when a rebate claim submitted in good faith is later denied, so that manufacturers do not avoid both the 340B discount and the Medicaid rebate?

Many states rely on 340B claims modifiers to distinguish 340B claims from non-340B claims and prevent duplicate discounts. Under the rebate pilot, covered entities will appropriately submit Medicaid claims with a 340B modifier when seeking a rebate from a participating manufacturer. However, if the manufacturer later denies that rebate, there is currently no standardized mechanism for removing or reversing the 340B modifier so the state Medicaid program can pursue its statutory Medicaid rebate. Without a clear process, pharmaceutical manufacturers stand to avoid providing lawfully obligated discounts.

Question: What steps is HRSA taking to mitigate administrative burden for 340B covered entities?

The APA requires federal agencies to administer programs in consistent and predictable ways. We are gravely concerned by variations across the manufacturers' letters to covered entities; the variation creates significant administrative burden for covered entities, which have only 61 days from notice to implement unprecedented changes in program management. Additionally, some manufacturers' letters impose heightened administrative burdens on covered entities. For example, as previously mentioned, when two covered entities submit the same claim, one manufacturer requires them to negotiate amongst themselves to determine who will receive the rebate.

Question: Is HRSA assigning current staff and/or hiring additional staff to exclusively manage the pilot program?

The pilot program is a large administrative undertaking that requires dedicated staff to monitor and operate properly. HRSA must enhance its capacity to ensure swift response to issues raised by covered entities and review manufacturers' implementation.

[3] Miu R, Kelly K, Nelb R. *Essential Data 2025: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2023 Annual Member Characteristics Survey*. America's Essential Hospitals. November 2025. essentialdata.info. Accessed Nov. 21, 2025.