AMERICA'S ESSENTIAL HOSPITALS

September 8, 2025

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

Re: 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program, Docket No. HRSA–2025–14998

Dear Administrator Engels:

Thank you for the opportunity to comment on the proposed rule. 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 from profit-seeking entities that would undermine this vital program. However, we are deeply concerned by the changes included in the Notice and believe these policies would undermine the intent of the 340B program—"to help covered entities stretch scarce federal resources as far as possible, allowing them to reach more eligible patients and provide a wider range of services."[1] We ask HRSA to rescind this misguided pilot program and ensure that 340B covered entities can continue to use the 340B program as it was intended.

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 more than 350 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.

America's Essential Hospitals members were part of 108 systems of care in 2022, 97% of which rely on 340B to serve their patients.[2] On behalf of these members, **America's Essential Hospitals urges HRSA to rescind its Notice announcing the availability of a 340B Rebate Model Pilot Program (Pilot Program) and related 340B Rebate Model Pilot**

[1] H.R. REP. 102-384(II), p. 12.
[2] Miu R, Kelly K, Nelb R. Essential Data 2024: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2022 Annual Member Characteristics Survey. America's Essential Hospitals. December 2024. essentialdata.info. Accessed Aug. 28, 2025.

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Program Frequently Asked Questions (FAQs) released on HRSA's website. Such a fundamental change to the program should not be implemented at all given the potential to directly harm patients and the essential hospitals they depend upon for affordable, high-quality care, and this rebate program certainly should not be so hastily implemented. It is unclear why HRSA believes there is such urgency to rush forward with a misguided policy and attempt to implement it alongside the Medicare drug negotiation timeline. A rebate program would neither correct any existing program deficiencies nor strengthen the 340B program in any way. In contrast, all it serves to do is harm patients and communities. **We disagree with HRSA's statement that the rebate model is a "methodical and thoughtful approach to ensure a fair and transparent 340B rebate model process." However, if HRSA nonetheless moves forward with the pilot, we urge the agency to adopt critical changes that would bolster the Notice's safeguards.**

Essential hospitals serve a vital role in their communities; our members provide a disproportionate share of the nation's uncompensated care, and three-quarters of their patients are uninsured or covered by Medicare or Medicaid. Essential hospitals provide state-of-the-art, patient-centered care while operating at an average loss of –9.0% compared with –2.8%at other U.S. acute care hospitals in 2022.[3] 340B discounts are critical to sustaining the safety net mission of essential hospitals. With their 340B savings, essential hospitals can target resources to services and programs that meet their community's unique challenges at nearly no cost to taxpayers. Essential hospitals have relied on 340B savings to support a mobile mammography unit, reduce prescription costs for patients, help manage the care of patients with hepatitis C, and provide wrap-around services to patients experiencing chronic homelessness that seek care in the emergency department, to name just a few examples.[4]

America's Essential Hospitals has submitted prior comment letters, including a May 2025 letter, opposing the establishment of 340B rebate models.[5] As with manufacturers' rebate proposals, the Pilot Program has the effect of appointing the fox to guard the hen house.

Rebates wrest critical programmatic decisions from the Department of Health & Human Services (HHS) and place them in the hands of individual drug manufacturers who are hardly impartial arbiters. Allowing the Pilot Program to move forward would add extraordinary inefficiency to the 340B program, impose unacceptable burdens on safety net providers, and cause significant harm to patients who will lose access to essential care—all to address potential duplications associated with the Medicare Part D Maximum Fair Price (MFP), as required under the Inflation Reduction Act (IRA),and which could be handled more effectively through other means.

Outside of the proposed Pilot Program, America's Essential Hospitals continues to applaud HRSA's efforts to prevent drug manufacturers from unilaterally imposing rebate models, protecting 340B covered entities' ability to serve their patients. **As HRSA rightly points out in the Notice, rebate models would fundamentally shift how the 340B program has operated for over thirty years**. We acknowledge HRSA's attempt to impose guardrails to create a transparent and fair process. However, there is no version of a rebate model where

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[3] Ibid.
[4] *Protect the Safety Net by Protecting 340B*. America's Essential Hospitals. https://essentialhospitals.org/wp-content/uploads/2025/02/Our-View-340B-February-2025.pdf. Accessed Aug. 28, 2025.
[5] Letter to Secretary Robert F. Kennedy Jr., "Sec. Kennedy—HRSA Rebate Guidance Letter," May 28, 2025. https://essentialhospitals.org/wp-content/uploads/2025/05/Sec.-Kennedy-HRSA-Rebate-Guidance-Letter-5-28-25.pdf. Accessed Aug. 28. 2025.

the manufacturers absorb the significant new complexities and burdens introduced, rather than the covered entities the 340B program is designed to protect. The current guidance falls short in defining a number of critical elements for a fair process. There are alternatives for the Centers for Medicare & Medicaid Services (CMS) to address any manufacturer concerns, real or contrived, regarding IRA compliance**. We urge HRSA to work with CMS to implement one of the alternatives we have previously suggested rather than rushing to create a rebate pilot to meet IRA deadlines.**

To ensure HRSA faithfully enacts the intent and purpose of the 340B Drug Pricing Program, we recommend HRSA consider the following areas to protect essential hospitals and their thoughtful stewardship of the 340B program:

- Rescinding of the pilot program
- Bolstering guardrails to protect covered entities
- Narrowing the scope of the pilot program to align with the IRA
- Ensuring sufficient transparency & opportunities for ongoing feedback
- Reducing pilot program burden on covered entities

Rescinding the Pilot Program

We acknowledge that HRSA has been facing pressure to address manufacturer rebate proposals and we appreciate HRSA's defense of the 340B program from endless attacks. Drug manufacturers have alleged in lawsuits that there is no way to avoid duplicate Medicare Fair Price and 340B discounts without a 340B rebate program. However, the D.C. Circuit Court of Appeals is actively in the process of considering the scope of HRSA's authority to permit rebates outside of the previously approved scope of AIDS Drug Assistance Programs (ADAPs). **HRSA should wait until the courts finally resolve the permissibility of rebates under the 340B statute.**

1. HRSA should not implement a rebate model because it is not explicitly authorized by statute

In addition to the outstanding legal questions, there are a number of other reasons that **HRSA should rescind the Notice establishing the Pilot Program.** First, the statute does not allow for rebate models and rebate policies. Any new guidance should reflect HRSA's past approval of rebates only applies to the ADAPs, which represent a unique situation. In 2020, 217 members of Congress on both sides of the aisle asserted that the rebate model is "inconsistent with HRSA's long-standing guidance that the 340B program is an up-front discount program."[6] More recently, in 2024, a bipartisan group of nearly 200 members reiterated that rebate models "severely undermine" the statutory purpose of the 340B statute to enable safety net providers "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[7] As evidenced in the congressional record and through these bipartisan efforts from Congress, the congressional intent of the 340B program is to allow access to up-front discounts.

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[6] Spanberger A., et al. Letter to Secretary Alex Azar. November 13, 2020. 201113_final_340b_hhs_letter.pdf. Accessed Aug. 23, 2025.
[7] Spanberger A., et al. Letter to Secretary Xavier Becerra. September 27, 2024. Quill-Letter-L20840-Letter-to-HHS-on-JJ-340B-Rebate-Model-Version-1-09-27-2024-@-03-08-PM.pdf.Accessed August 21, 2025.

2. HRSA has already made a policy decision to reject rebate models

Second, HRSA has already made the policy decision to deny manufacturers' requests to enact rebate models, recognizing that manufacturers have "overstate[d] the need to establish a 340B rebate model to meet their obligations under the Negotiation Program."[8] Manufacturers "do not need to unilaterally impose cash rebates [...] to ensure program integrity."[9] Allowing rebate programs would "upend the 340B Program as it has operated for thirty-three years,"[10] and "covered entities would be forced to pay a higher price point up front for every purchase."[11] .

The sole time HRSA has previously approved rebates was for the limited purpose of enabling ADAP participation in 340B—an extreme circumstance where the purchasing systems of ADAPs created difficulty in accessing up-front discounts. There are no similar grounds that warrant rebates through the Pilot Program. HRSA has "provided a rational explanation" for the differential treatment of ADAPs.[12] Approval of rebates for ADAPs does not require or merit approval of rebates in other circumstances. **HRSA cannot now backtrack on its policy position on rebates when no new arguments or considerations have been raised in favor of rebates.**

3. HRSA has not provided sufficient notice and opportunity for feedback

Third, **the Pilot Program results in a significant change in covered entities' rights and responsibilities without prior notice or opportunity for feedback.** There are three key issues here: (1) the Pilot Program took effect on the date the Notice was published with no prior warning; (2) the Notice indicates that the Office of Pharmacy Affairs (OPA) "is under no obligation to respond to or act in the comments,"[13] and (3) covered entities will have to switch from upfront discounts to rebates within the next four months and comply with specific manufacturer proposals that they will not have notice of until after October 15. **Unlike for manufacturers, participation in the Pilot Program will be mandatory for covered entities**. The Pilot Program will result in substantial financial hardships for safety net providers, yet they are being forced into the program without ample notice or safeguards.

Under the Pilot Program, hospitals will be forced to draw from already limited cash reserves or funds budgeted for other operations to pay full drug prices up front. The fundamental difference between a discount and a rebate model is the cash flow impact. Currently, even under replenishment models, covered entities pay the full commercial price for a drug no more than once. But under the rebate model, covered entities will have to pay the full commercial price every time they make a purchase. As the D.C. district court explained, "a cash rebate model shifts the initial outlay for drug costs from manufacturers to covered entities . . . . Cash rebates would require providers to spend significantly more up front on each transaction, in contrast to the replenishment model, under which covered providers typically pay commercial prices only

[8] Brief of Defendants at 23, *Eli Lilly & Co., et al. v. Kennedy*, No. 1:24-cv-03337-DLF (D.D.C. Mar. 17, 2025).
[9] Ibid.
[10] Ibid.
[11] *Eli Lilly & Co., et al. v. Kennedy*, No. 1:21-cv-02608-DLF at 25 (D.D.C. May 15, 2025).
[12] Ibid.
[13] 90 Fed. Reg. 36163, 36163.

once . . . . That financial burden on providers has factored into HRSA's preference for up-front discounts since the 340B program's inception."[14]

Many hospitals participating in the 340B program are prohibited from participating in group purchasing organizations that allow providers to purchase drugs at less than the Wholesale Acquisition Cost (WAC). Non-340B providers will have access to Medicare Fair Price for these drugs under the drug negotiation program. But340B hospitals, eligible because of the low-income patients they serve, will be the only providers paying the WAC. Initial purchasing costs could double compared to 340B prices, which directly impacts covered entities' ability to serve their patients. If the scope of eligible drugs expands, the harm will grow.

The purported 10-day window for receiving discounts is already significant and could be much longer if manufacturers deny or delay reimbursement in the interest of padding their bottom lines. Manufacturers have engaged in such stall tactics before: for example, when they have implemented reporting requirements for accessing discounted drugs through contract pharmacies. Without clear and prescriptive Pilot Program rules and substantial penalties for non-compliance, manufacturers would have the ability to withhold or deny rebates, such that hospitals may not be reimbursed for 100% of the rebates they are rightly owed under the law. **HRSA should not move forward with a Pilot Program without giving covered entities a robust opportunity to have their feedback incorporated into program design.**

4. A rebate program creates significant administrative burden

Fourth, despite HRSA's intent, the Pilot Program will come with a substantial administrative burden on covered entities. The Pilot Program will require covered entities to change existing arrangements with many of their contracted vendors, across their internal and external vendor systems, and with each of the manufacturers to track and reconcile rebates as well as purchasing and accumulation under 340B program rules on the provider side. HRSA is mistaken in attesting that no costs will be passed through to covered entities.[15] **In practice, significant investments by covered entities will be required whether rebates are more limited in scope, as under the Pilot Program, or more expansive, as under manufacturers' recent proposals.**

We appreciate that HRSA proposes to address this concern, but the proposed approach unfortunately will not be sufficient. Under the Pilot Program Notice, manufacturers must attest in their plan "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."[16] But this part of the process does not get to the costs of changing all of the covered entity processes involved in producing this information, reconciliation of rebates, and ensuring ongoing compliance with 340B rules. **While manufacturers may front the bill for IT costs as required under the Pilot Program, additional costs of time and labor will accrue to the covered entities themselves.** As each participating manufacturer will be allowed to develop their own rebate program and processes, the time and labor associated with compliance will be additive each time a new manufacturer develops a rebate program. Keeping track of multiple rebate programs

[14] Eli Lilly & Co., et al. v. Kennedy, No. 1:21-cv-02608-DLF at 25 (D.D.C. May 15, 2025).
[15] 90 Fed. Reg. 36163, 36164.
[16] Ibid.

adds an undue burden on covered entities, while manufacturers implement only their own systems.

HRSA's FAQs refer to some of the complexities that covered entities will face but do not adequately address or support them. For example, the FAQs state that "[c]overed entities should have access to the real-time rebate status of a claim, so they can easily reconcile claims submitted with rebates paid."[17] Even if most manufacturers wind up using the same IT system, there may be different requirements and processes that they implement and that providers will have to work with their vendors to adopt. The FAQs also acknowledge the likely challenge of delayed or denied rebates, but again HRSA has not proposed efficient and enforceable methods to address the issue. The FAQs indicate that if it takes longer than 10 days for a rebate to be paid, "covered entities [or the IT platform vendor] and manufacturers should work to resolve the issue."[18] And if the parties cannot reach a consensus, the covered entity must email a general HRSA email.[19]

This proposed system is backward—covered entities will have to pay for the time and resources to negotiate payment when manufacturers are the ones who are failing to comply with the program. Such administrative costs will fall squarely on the covered entities, many of whom are operating on slim or negative margins. Additional costs will also be imposed on HRSA to read and respond to all rebate reimbursement issue emails at a time when the federal government has been staunchly focused on reducing burden.

5. HRSA and CMS have alternative ways to identify 340B Drugs

Fifth, we acknowledge that efforts must be made by HHS to address 340B and MFP deduplication. But there are superior ways to address this concern that do not require a rebate program, as we and other hospital associations have previously proposed to HHS.[20] CMS is working on a 340B repository as outlined in the 2026 Physician Fee Schedule (PFS) proposed rule that could be another option for future program years. **HRSA should first consider alternatives to the Pilot Program that would meet the same objectives as the pilot without causing a fundamental shift in the 340B program.**

For all of the aforementioned reasons, HRSA should rescind the Notice implementing the Pilot Program.

Bolstering Guardrails for Covered Entities

We appreciate HRSA's efforts to limit scope and attempt to limit complexity, but significant new burden and disruption is inevitable, especially when HRSA is setting up a fundamentally different program for accessing mandated 340B discounts in an incredibly short period of time. **Therefore, if HRSA does indeed proceed with a Rebate Pilot, we urge HRSA to**

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[17] *340B Rebate Model Pilot Program*. Health Resources & Services Administration, https://www.hrsa.gov/opa/340b-model-pilot-program. Accessed August 21, 2025 [hereinafter "*340B Rebate Model Pilot Program FAQs*"].
[18] *Ibid.*
[19] *Ibid.*
[20] Joint Letter Regarding MDPNP Draft Guidance, July 2, 2024, at https://essentialhospitals.org/wp-content/uploads/2024/07/Joint-Comments-on-5.3.24-IRA-Draft-Guidance-7.2.24.pdf; Joint Comments on Proposed Rules Relating to the Medicare Prescription Drug Inflation Rebate Program, Sep. 9, 2024, at 090924-joint-comments-on-proposed-inflation-rebate-rule.pdf.

more narrowly define the pilot scope and to enact further guardrails to deter manufacturer noncompliance.

6. HRSA Should Retain Important Guardrails in the Current Notice

We appreciate HRSA's establishment of certain guardrails in the Pilot Program that aim to reduce the burden on covered entities, and we urge the agency to maintain these elements in the face of anticipated requests to change them. As further discussed below, these elements include:

- limiting the requested data to a defined set of readily available pharmacy claim fields
- not permitting manufacturer denials of rebates based on claims of diversion or Medicaid duplicate discounts, and
- requiring that rebates be paid to the covered entity within 10 calendar days of data submission.

HRSA's criteria for manufacturer rebate plans also raise issues of significant concern with respect to data privacy and security laws. The criteria will only be as effective as HRSA's review and enforcement of compliance, as discussed below, but these guardrails are nonetheless important steps and must be retained.

7. HRSA should bolster program guardrails to ensure manufacturers provide legally mandated access to ceiling prices

Having acknowledged the significant upheaval to covered entities and significant concerns about cash flow challenges for safety net providers, it is incumbent upon HRSA to be proactive in monitoring compliance, to enforce the terms of the pilot, and to clearly articulate for all stakeholders what will trigger enforcement actions. We appreciate that HRSA stated in the notice and reiterated in the FAQs that OPA has the right to revoke the rebate model approval for a manufacturer if they are not complying with program policies. However, the identified instances when HRSA would revoke approval remain vague. **We urge HRSA to clarify penalties and other tools to ensure manufacturers provide lawfully mandated access to 340B discounts.**

a. HRSA should clarify enforcement standards and penalties for non-compliance.

A particularly critical element of the pilot is HRSA's requirement that manufacturers provide the rebate within 10 days of claim submission. If manufacturers do not comply with this deadline, they are violating their obligation and overcharging covered entities. In the Notice, HRSA indicates that revoking approval to participate in the model is the intended enforcement mechanism. However, in the recent FAQs, HRSA elaborated that if a manufacturer "*trends towards*" not paying rebates within 10 days of submission or if it "*is unable to timely resolve* rebate reimbursement issues" that its approval may be revoked. HRSA's policy does not go far enough to determine clear parameters for the term "trends toward" nor the term "unable to timely resolve."[21] **The agency should provide additional, and more specific guidance, on when it will revoke Pilot Program participation for non-compliance.** The Pilot Program is voluntary for and of significant benefit to manufacturers. If they cannot comply,

[21] *340B Rebate Model Pilot Program FAQs.*

then revocation of participation should be swift. A vague mention of revocation on its own is not a meaningful deterrent, nor is the term "trends towards" clearly defined. **HRSA should also proactively monitor whether manufacturers are denying rebate claims, including through regular manufacturer reports to OPA as contemplated under the Notice.**

HRSA should also consider interim steps, such as monetary penalties, to deter non-compliance before revoking program participation altogether. For example, OPA can refer manufacturers to the HHS Office of Inspector General to impose civil monetary penalties on manufacturers when they knowingly and intentionally charge a covered entity a drug purchase price that exceeds the 340B price.[22] Penalties occur for each instance of overcharging.[23] Repeated instances of missing the rebate payment deadline could be referred to OIG in addition to resulting in ending participation in the Pilot.

As discussed more in the context of appropriate appeals mechanisms, the recent FAQs state that "If a claim takes longer than 10 days for a rebate to be paid, covered entities and manufacturers should work to resolve the issue." Another FAQ provides that covered entities "should first contact the manufacturer and IT platform vendor to report concerns. If after attempting to work with the manufacturer a covered entity cannot resolve the issue with the manufacturer, the covered entity should email 340BPricing@hrsa.gov with the details of its concern." Manufacturers have the obligation to pay rebates within 10 days ; HRSA should ensure manufacturers have the primary responsibility for payment compliance, including the responsibility to check for an IT issue and take steps to resolve delays. **While covered entities should have an effective means to contact HRSA about noncompliance, the onus to resolve delays must lie with the manufacturer.**

There are other program criteria that will be meaningful only if there is proactive HRSA verification of compliance and enforcement. HRSA requires that manufacturer plans provide "assurance" as to compliance with a number of issues, e.g., IT system compliance with data privacy and security laws. The manufacturer plans are limited to 1,000 words, so many details will be left to implementation. Due to the brevity required, we are concerned HRSA and covered entities alike will not have sufficient detail to ensure compliance with these requirements. Other criteria relate to HRSA's attempt to limit burden on covered entities, e.g., that the plan should allow the covered entity to use existing distribution mechanisms, or the IT platform should have capability to provide real-time reconciliation reports to covered entities. HRSA should similarly revoke participation for failure to meet these requirements as it states it would do if manufacturers delay or deny rebates.

b. HRSA should explicitly clarify when rebates can be denied.

We applaud HRSA taking a critical step in this notice by prohibiting manufacturers from denying 340B rebates based on compliance concerns with diversion or Medicaid duplicate discounts. HRSA is the proper arbiter of compliance with those 340B program rules and those issues have nothing to do with the IRA compliance that is driving the timeline of the pilot. But HRSA has not provided an exclusive list of the grounds for which denials would be permitted. It is no secret, given the ongoing rebate litigation, that manufacturers desire to implement rebates for a much broader set of reasons than the Pilot Program seems to envision.

[22] 42 U.S.C. § 256b(d)(1)(B)(vi).
[23] 42 C.F.R. § 10.11.

HRSA should modify the Notice to specifically identify the limited scenarios in which manufacturers can deny 340B rebates, leaving no discretion to manufacturers. Those scenarios should be limited to when (1) basic claims information is missing or (2) multiple 340B entities submit a rebate for the same claim. Still, even if a manufacturer denies a claim for one of these reasons, a covered entity should be allowed to correct the claim and resubmit it. Adding these specifications to the Pilot Program in this way would protect covered entities by preventing manufacturers from denying 340B rebate claims in arbitrary and self-serving ways, and put the onus on the manufacturers who are benefitting from the Pilot to identify appropriate reasons for denials.

If HRSA opts to continue listing out the instances where manufacturers cannot deny 340B rebates, additional scenarios should be added to that list. For example, HRSA should not allow manufacturers to deny claims that do not comply with the companies' contract pharmacy policies. The Pilot Program should not be another tool for manufacturers to restrict contract pharmacy access. In addition, manufacturers should not be allowed to deny 340B rebates if a covered entity does not replenish the full package size within 45 days. **To ensure that all inappropriate grounds for denial are identified, HRSA should solicit additional feedback from covered entities.**

c. HRSA should establish a claims denial dispute process that efficiently enables covered entities to resolve access to legally-mandated ceiling prices

We are concerned that the Pilot program notice and FAQ do not provide sufficient clarity on how claim disputes will be resolved. It is unrealistic for the agency to rely on the administrative dispute resolution (ADR) process to adjudicate inappropriate denials. The ADR process is far too lengthy to quickly and adequately address inappropriate denials—the process could be longer than the pilot term. The alternative provided in the Notice, which affords covered entities "opportunities to raise concerns with OPA if there are issues"[24] is no more realistic, however, than the ADR process. This language is vague and does not make clear the process the agency will take when a complaint is lodged, the timing before there will be some resolution, when it will get its rebate if improperly denied, etc. It also fails to provide adequate disincentive for improper denials in the first place. **HRSA must provide greater clarity on the denial process and update the Notice accordingly**.

The FAQs now provide slightly more detail, but still don't address these key concerns. "If after attempting to work with the manufacturer a covered entity cannot resolve the issue with the manufacturer, the covered entity should email 340BPricing@hrsa.gov with the details of its concern." **We urge HRSA to put additional consideration into this process and ensure that adequate resources are allocated to resolve the anticipated denials**.

HRSA should also consider using covered entity reports and inappropriate denials to determine if the agency should revoke manufacturer participation. Such a mechanism would help deter some level of inappropriate denials. There are numerous other considerations; for example, HRSA should enable covered entities to group denials for joint consideration to speed resolution and reduce administrative burden; HRSA could create a template form for submission of reports of inappropriate denials; etc. Ultimately, given concerns about the robustness of any dispute process that might be set up quickly and for a pilot, we urge HRSA to follow our previous request and create a limited list of permissible reasons for denial to reduce the number of likely denials that must be subject to the process.

[24] 90 Fed. Reg. 36163, 36165.

Narrowing the Scope of the Pilot Program to Align with the Medicare Drug Price Negotiation Program

We appreciate HRSA taking steps to limit the scope of the rebate pilot, particularly to target drugs implicated in the Medicare Drug Price Negotiation Program (MDPNP). HRSA's timing of implementation of the pilot, the scope of the drugs at issue, and HRSA's exclusion of diversion and Medicaid duplicate discount issues from reasons for denial of rebates all make clear that HRSA is implementing this pilot to address manufacturer concerns regarding duplicate Medicare Part D MFP for the 10 drugs at issue and 340B discounts. We acknowledge the challenges with ensuring compliance with the requirements of the IRA and **urge HRSA to narrow the scope of the pilot further to exclusively target those requirements.**

8. HRSA Should limit the scope to drugs paid for by Part D for 2026

Given that the pilot is a test of limited scope anyway, and given the potential for many unknown and complex issues that could result in delay and financial pressure on covered entities, it is unclear why HRSA did not further align the pilot with the scope of the IRA program—namely, limiting the scope to only drugs paid for by Medicare Part D and only to retail drugs, rather than including clinic and physician administered drugs. **HRSA should reconsider and limit the initial pilot to Part D retail drugs for the first year**. There will be significant operational issues to test, not to mention understanding the impact of the program on covered entities, and HRSA would be best-served by testing the pilot in a more limited fashion.

The narrower scope would reduce burden and complexity for covered entities, consistent with Executive Order 14192, which calls on agencies to "alleviate unnecessary regulatory burdens."[25] The narrower scope will limit the volume of claims subject to potential denials, the complexities created by including clinic and physician-administered drugs, and the complexities created by including Medicaid drugs. Covered entities would still face burdens related to changing purchasing and compliance systems, but reducing the number of units that must go through reconciliation will reduce reporting and other burdens.

There are a number of complexities caused by HRSA extending the rebate pilot outside of Medicare. HRSA did not address Medicaid in the Notice, and the FAQs shifted to covered entities the obligation to figure out the complexity of including drugs for Medicaid patients in the pilot. HRSA also does not address, for example, instances where a provider has chosen or a state requires that Medicaid be carved out from 340B—must covered entities that currently can purchase drugs for Medicaid patients at GPO prices now spend easily double that amount to purchase those drugs at WAC?

The Notice is also silent on whether the Pilot would involve only retail drugs. The FAQs subsequently clarified, however, that the Pilot Program is applicable to all negotiated covered outpatient drugs, "including physician- or clinic-administered drugs."[26] The 10 drugs selected for negotiation under Initial Applicability Year 2026—and thus those that may be included in the Pilot Program—are Part D drugs which are not administered in a clinic or physician setting.

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[25] Executive Order 14192, "Unleashing Prosperity Through Deregulation," Federal Register, Feb. 6, 2025 (90 FR 9065). https://www.federalregister.gov/documents/2025/02/06/2025-02345/unleashing-prosperity-through-deregulation. Accessed Aug. 28, 2025.
[26] *340B Rebate Model Pilot Program FAQs.*

HRSA can and should avoid these complexities by limiting the Pilot to retail drugs for Medicare Part D patients.

Ensuring Sufficient Transparency & Opportunities for Ongoing Feedback

HRSA should prioritize transparency throughout the Pilot Program application and implementation process. There are a number of ways HRSA can ensure all stakeholders—including both covered entities and manufacturers—understand how the rebate pilot will work and how it will be evaluated moving forward.

9. HRSA should publish fully approved rebate plans

Manufacturers' fully approved rebate plans should be published on the HRSA website for public viewing. The FAQs indicate that the agency will publish "a *summary* of all approved rebate model plans on its website."[27] But merely publishing a summary of manufacturers' plans does not go far enough; the full plans as approved should be available for the public to review. Publishing the full plans will enable covered entities to provide immediate feedback to HRSA if programmatic details set forth in manufacturer plans raise additional challenges or burdens; assist covered entities in preparing for implementation in what is already a remarkably short window, and create additional public accountability that will hopefully influence the thoughtfulness and quality of manufacturer plans.

10. HRSA should publish plans for conducting assessment of the pilot program

As discussed below, we have serious concerns about any extended or expanded implementation of rebate models. **HRSA should develop and solicit feedback on a detailed plan for conducting an assessment of the pilot** as well as criteria for evaluating whether extension and/or expansion of the Pilot would be appropriate. Specifically, HRSA should (1) specify what data and reports will be collected, (2) define what an effective pilot program entails; and (3) lay out a plan to solicit ongoing feedback from covered entities and stakeholders. HRSA reiterates in the FAQs that, at this time, there is no clear plan to solicit feedback from covered entities and stakeholders; rather, the agency plans to consider such processes once the pilot has been fully implemented.[28]

Further Steps to Limit Burden to Covered Entities

11. HRSA Should Not Approve Plans Going Beyond Stated Criteria

We appreciate HRSA's notice limiting the amount of information manufacturers can require covered entities to submit as part of a rebate claim. However, we are concerned that the guidance also authorizes manufacturers to submit plans proposing additional data requirements beyond those included in the pilot criteria. Specifically, the Notice indicates that

[27] *Ibid.*
[28] *Ibid.*

any "plans that exceed or go beyond these criteria should include detailed justification and will be subject to additional review by OPA prior to implementation."[29] The FAQs then explicitly state that "[m]anufacturers who submit plans may request to collect additional data" and that "OPA will review such requests."[30]

HRSA should not approve any plans that go beyond the stated criteria in the Notice; this is not a "choose your own adventure" program, it is a limited Pilot Program that should remain narrow with common criteria across participants. The benefit of outlining the criteria for the program, for stakeholder feedback as well as for limiting burden created by variations across manufacturers in data reporting as well as requests for unnecessary data, is undermined if HRSA allows manufacturers to create modified programs.

If HRSA nonetheless moves forward with approving plans with additional data collection requirements, HRSA should seek feedback from stakeholders on the proposed data fields and provide public guidance on its rubric for determining whether plans that deviate from stated criteria should be approved or denied.

12. HRSA Should Not Permit Changes to Reporting Requirements or Significant Changes in Implementation of Program Criteria Mid-Pilot

Experience with manufacturers and their vendor for data collection related to contract pharmacy reporting requirements has demonstrated that these companies have a proclivity to change terms of engagement with the reporting system as well as requirements for timing of claim submission, etc., with little to no notice or transparency. **We urge HRSA to make clear that as a condition of participating in the pilot, the manufacturers and their vendor cannot unilaterally change terms and implementation details mid-course , and at the very least without HRSA notice and approval.**

13. HRSA Should Not Accept Plans for Consideration After September 15

In the FAQs, HRSA states that "manufacturers who have drugs selected under IPAY 2026 with an agreed upon maximum fair price, may submit plans for consideration after September 15, 2025, but any potential approval would have an effective date later than January 1, 2026." **HRSA should not permit manufacturers/drugs to be added to the Pilot Program mid-year.**

Covered entities will have to work with multiple internal and external vendors and systems to implement the Pilot, including opening up related contracts, etc. There is already going to be a short window of implementation that will necessitate allocating unanticipated resources to the Pilot with the manufacturers who get their plans in on time and approved. An unexpected addition of a drug to the program would cause additional disruption and financial strain. This program is optional for manufacturers. If they want to participate in the first year, they should meet the deadline.

14. HRSA Should Permit Covered Entities to Limit WAC Purchasing Wherever Possible for Drugs Subject to the Pilot

[29] 90 Fed. Reg. 36163, 36164.
[30] *340B Rebate Model Pilot Program FAQs.*

CMS went through an arduous, and oftentimes controversial process, to negotiate the MFP for the 10 selected drugs. Non-340B entities will not be required to pay WAC at any time for these drugs, and 340B hospitals should be treated the same. **HRSA should also work with CMS as needed to enable covered entities to buy drugs under the Pilot at MFP rather than WAC.**

There is no discernible reason why 340B hospitals would have to pay the higher WAC instead of the lower MFP; requiring hospitals to pay the higher cost will put further strain on their already tight budgets as there is almost always a 50% or more difference between the two. Again, the rebate pilot is a benefit to manufacturers and is subject to HRSA's discretion, so it would not be unreasonable for HRSA to require manufacturers to provide access to MFP and then reconcile up or down depending on whether the 340B price is less or greater than the MFP. HRSA can also coordinate with CMS as needed.

Covered entities also purchase non-340B drugs through the prime vendor program and are able to access sub-WAC pricing for these products. To ensure covered entities maintain access to these discounts, **HRSA should also clarify that covered entities purchasing non-340B drugs through the Prime Vendor program can continue to access sub-WAC pricing for drugs under the Pilot where applicable**

15. HRSA Should Not Expand the Pilot Program But Instead Focus on Alternatives to Address Medicare and 340B Program Compliance Without Undermining the 340B Program's Fundamental Benefit

The Notice states that "[a]fter assessment of the pilot, which will include OPA's evaluation of data and reports from the participating manufacturers on the effectiveness of the model and covered entity and other stakeholder feedback, OPA may consider expanding the rebate pilot to other drugs purchased under the 340B program." The FAQs provide concerning clarity that the pilot may at some point be expanded to drugs that have not been selected for negotiation.[31]

d. HRSA should not expand this pilot program to include other drugs

Because HRSA asserts that this Pilot Program was created primarily to address 340B and MFP deduplication, expanding the program to include drugs not subject to Medicare drug price negotiations is not warranted or appropriate. Moreover, there are alternatives to address 340B and MFP deduplication; **HRSA and CMS should work together to implement alternative deduplication methodologies that do not undermine the 340B Program.**

Regardless, given the enormous implications of expanding the program to other drugs, we strongly discourage HRSA from expanding the program whatsoever. As the number and types of drugs eligible for the Pilot Program increases, the negative impact on covered entities will increase exponentially; specifically, the upfront costs covered entities will have to provide on an expanded scope of drugs will be prohibitive. Covered entities will also see vastly higher administrative costs as they work to comply with a larger number of programs from multiple manufacturers. Covered entities are already facing significant financial strain exacerbated by recent federal legislative and administrative changes, and they will be unable to secure the capital needed to pay upfront costs for a significant number of drugs.

[31] *340B Rebate Model Pilot Program FAQs.*

Moreover, under no circumstances should the Pilot Program be expanded beyond drugs on the Medicare Drug Price Negotiation list. Lessons learned from this limited Pilot Program would be insufficient to overcome the many valid concerns HRSA has raised in withholding approval of broader applications of rebates. HRSA has publicly and repeatedly defended its denials of more expansive manufacturer rebate programs on numerous grounds. Any expansion of the Pilot Program beyond drugs on the Medicare Drug Price Negotiation list would result in a wholesale reversal of HRSA's longstanding policy with respect to rebates, requiring extraordinary justification and steps to mitigate potential harms to covered entities.

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America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Evan Schweikert, at 202-585-0124 or eschweikert@essentialhospitals.org.

Sincerely,

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