April 20, 2026

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 20857

Ref: HRSA-2026-03042: Request for Information: 340B Rebate Model Pilot Program

Dear Administrator Engels:

Thank you for the opportunity to comment on the request for information (RFI) regarding a 340B Rebate Model Pilot Program. For the past two years, we have shared with the agency our serious concerns about rebate models and the harm that they would cause to the patients that our hospitals serve. These models are not necessary to implement the Medicare Drug Price Negotiation Program (MDPNP) and are nothing more than an attempt by drug manufacturers to boost their profits at the expense of safety net providers. Now that federal courts have stopped the Health Resources and Services Administration (HRSA) from implementing its proposed rebate pilot because it did not fully consider the concerns of covered entities, **we urge HRSA to review and respond to our evidence of rebate models' real-world impact before further upending the 340B Drug Pricing Program.**

Below, we summarize our general concerns with rebate models and provide detailed responses to the questions that the agency raised based on our members' real-world experience preparing for the rebate pilot. Overall, **we estimate continuing HRSA's proposed rebate model would result in $1.5–1.6 billion in direct costs and $3.7–$4.6 billion in total costs for hospitals in 2027 alone. These burdens would disproportionately harm essential hospitals, which account for 9% of 340B hospital covered entities but would bear approximately 15% of the added costs.**

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 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.

essentialhospitals.org
AMERICA'S ESSENTIAL HOSPITALS
401 Ninth St NW Ste 900
Washington DC 20004
t: 202 585 0100
f: 202 585 0101
e: contact@essentialhospitals.org

Essential hospitals are committed to serving people in all communities that need access to quality care. Despite making up just 6% of hospitals nationwide, essential hospitals provide 29% of the nation's charity care. About three-quarters of the patients our members serve are uninsured or enrolled in Medicaid or Medicare.[1] In addition, nearly two-thirds of essential hospitals provide services to rural patients and communities.[2] To meet patient needs, essential hospitals constantly work to improve quality and access, including access to essential services that would otherwise be unavailable in their communities, all while lowering health care costs and spending.

Unfortunately, much of the care that essential hospitals provide to their communities is uncompensated or under-reimbursed. In 2023, essential hospitals reported $22.4 billion in unpaid costs of care. These costs contribute to the financial challenges affecting essential hospitals. In 2023, members of America's Essential Hospitals had an aggregate operating margin of -7.1%, more than three times lower than the aggregate operating margins for all other hospitals (-2.3%).[3]

The 340B program is instrumental in allowing essential hospitals to stretch scarce federal resources, reach more eligible patients, and provide a wider range of services, exactly as Congress intended. Our members use 340B savings to support patient care services that would otherwise be unavailable in low-margin settings, including oncology and infusion services for uninsured patients, behavioral health programs, trauma and emergency preparedness capacity, care coordination for high-risk patients, and access to discounted or free medications.[4] For more than 30 years, this program has worked as Congress intended by making sure that drug manufacturers do not overcharge providers that fill a safety net role.

Recently, the 340B program's value has grown because for-profit drug manufacturers continue to increase prices beyond the rate of inflation. To rein in drug prices, Congress and President Trump have implemented several new policies, including MDPNP and most-favored nation policies that are intended to build on the 340B program's success. **Unfortunately, several drug manufacturers have tried to use the implementation of these policies as a pretext for shirking their responsibilities to provide up-front discounts through the 340B program.** Although spending on 340B covered drugs is less than 3% of global drug company revenues, for-profit drug companies have been ruthless in their attempts to boost their profits at the expense of safety net providers.[5]

Drug manufacturers tried to implement rebate models before the MDPNP implementation, but these efforts intensified in 2024, when multiple drug manufacturers—including Johnson & Johnson, Sanofi, Eli Lilly, Nfovartis, and Bristol Myers Squibb—sought to unilaterally impose rebate arrangements that would require covered entities to purchase drugs at full price and later submit claims for reimbursement. At the time, **HRSA appropriately determined that**

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[1] 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 March 31, 2026.

[2] America's Essential Hospitals. Policy Brief: Essential Hospitals Ensure Access to Care in Rural Areas. March 2025. https://essentialhospitals.org/policy-brief-essential-hospitals-ensure-access-to-care-in-rural-areas/. Accessed Feb. 19, 2026.

[3] Ibid.

[4] Ibid.

[5] American Hospital Association. Fact Sheet: The 340B Drug Pricing Program. October 2025. https://www.aha.org/system/files/media/file/2025/10/fact-sheet-the-340b-drug-pricing-program-r-10-2025.pdf. Accessed March 31, 2026.

such unilateral actions violated drug manufacturers' statutory obligations and purchasing agreements, emphasizing that rebate models would fundamentally alter the structure of the 340B program, impose significant administrative costs, and shift substantial financial burden onto safety net providers. Drug manufacturers attempted to justify these proposals by citing concerns about duplicate discounts arising from the MDPNP, but both HRSA and federal courts have recognized that rebates are not the only—or necessary—solution to address these issues.

Despite broad and consistent stakeholder opposition, HRSA announced a limited rebate pilot program in July 2025 focused on drugs subject to negotiation in the MDPNP. With the pilot, HRSA acquiesced to drug manufacturer demands to upend 340B program operation. Additionally, HRSA imposed unnecessary administrative burden on providers and require covered entities to front hundreds of millions of dollars to drug manufacturers while they waited for rebates to process. America's Essential Hospitals raised these legitimate concerns to HRSA through multiple letters, but after the agency failed to address them, we joined a federal lawsuit to compel HRSA to follow its responsibilities under the Administrative Procedure Act to adequately consider the impact on covered entities.

Now that federal courts have stopped the implementation of a rebate pilot, we appreciate HRSA's effort to reassess the value of rebate models by requesting information from stakeholders about the harm that these models would cause. **We urge HRSA to use data collected from this RFI to reevaluate whether rebate models are in the public's interest and to respond to stakeholder feedback before taking additional action to implement a rebate pilot.**

Unfortunately, HRSA has already issued an information collection request (ICR) that signals that the agency may expand its initially proposed rebate program in 2027 with additional drug manufacturers.[6] This action appears at odds with the district court for the District of Maine's ruling to consider stakeholder feedback before moving forward with implementation. Additionally, it is further evidence of the judge's ruling that HRSA is attempting to "fly the plane before they build it."[7]

America's Essential Hospitals is willing to continue to work with HRSA to support its efforts to oversee and protect the 340B program. We hope that these comments can be the beginning of further, meaningful dialogue with the agency to ensure that the 340B program can continue to work as intended.

General Concerns with Rebate Models

HRSA's RFI omits some of the most important policy questions that must be considered to determine whether rebate models are in the public's interest, including:

- What is the effect of rebate models on the ability of covered entities to provide access to all care that their patients need?
- Are rebates necessary to implement the MDPNP?

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[6] *Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation,* OMB No. 0906-NEW, 91 Fed. Reg. (Feb. 17, 2026).
[7]American Hospital Association v. Kennedy, No. 2:25-cv-00600-LEW, PageID #: 1185 (D. Me. 2025)

- Is HRSA's approach to a "pilot" the most appropriate way to make major structural changes to the 340B Drug Pricing Program?

Below, we comment on these overarching questions before responding to the specific concerns that HRSA raised in its RFI.

Overall, we find that rebate models would directly harm patients by limiting access to the full range of services that essential hospitals provide. **Based on this harm alone, we urge HRSA to reject any version of a rebate model.**

We have been particularly concerned with HRSA's proposed 340B rebate pilot program because it is based on a flawed assumption that rebate models are necessary to implement MDPNP. **At a minimum, we urge HRSA to pause and review the experience of the MDPNP and providers' experience preparing for the rebate pilot to make an evidence-based decision about the need to upend the 340B Drug Pricing Program.**

HRSA's proposed rebate model was flawed from the start because it attempted to make major structural changes to the 340B Drug Pricing Program through a "pilot" mechanism that was mandatory for covered entities. **We urge HRSA to respect congressional intent and not make mandatory structural changes to the program without explicit authorization from Congress.**

Harm to Patients

The 340B program exists to help safety net providers "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[8] A rebate model inverts that purpose. By forcing essential hospitals to purchase drugs at full wholesale acquisition cost and wait for reimbursement, rebate models drain the operating funds that hospitals use to sustain services for their most vulnerable patients—redirecting money that currently funds uncompensated care directly into drug manufacturer cash flow.

HRSA's RFI includes one question about how rebate models would affect patient access to covered drugs, but the agency failed to consider how rebates would affect access to the full range of services that essential hospitals provide. A rebate model not only would affect access to prescription drugs, but also limit access to the wide range of services that essential hospitals provide to low-income and uninsured patients. These include services that are necessary to access prescription drugs in the first place, whether to diagnose and prescribe treatment, or to access professionals to administer complex drugs.

a. Rebate models will eliminate or curtail services on which uninsured patients depend.

The 340B program allows covered entities to provide uninsured patients drugs at little or no cost, cross-subsidized by revenue from insured patients billed at full price for drugs purchased at the 340B discount. A rebate model breaks this mechanism. Under a rebate model, wholesaler pricing reflects the full wholesale acquisition cost rather than the 340B ceiling price, meaning the discounted price is no longer visible in the pharmacy billing systems that hospitals use to extend sliding-scale fees to uninsured patients. Programs our members use to provide oncology drugs, infusion services, and other high-cost therapies to uninsured patients are placed at direct financial risk; only an up-front discount structure makes these services operationally feasible.

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[8] H.R. Rep. No. 102-384(II), at 12 (1992).

b. Expected changes in uninsured rates will accelerate these harms.

Recent federal legislation reducing Medicaid eligibility and marketplace subsidies is expected to substantially increase the number of uninsured Americans who depend on safety net providers. The Congressional Budget Office (CBO) projects 4.2 million more uninsured Americans in 2034 due to the expiration of enhanced premium tax credits and 10 million uninsured due to Medicaid eligibility changes.[9] Using this CBO data, we anticipate hospital uncompensated care costs will rise by $466 billion over 10 years.

340B savings are even more critical to sustaining uncompensated care. **HRSA should not undermine the financial foundation of safety net hospitals at precisely the moment their uninsured patient load is set to increase.**

c. Rebate models will undermine emergency preparedness.

A rebate model will reduce essential hospitals' available cash on hand, which will have far-reaching effects on drug availability beyond rebated products. The up-front discount model enables essential hospitals to maintain on-hand supplies of high-cost, low-utilization emergency drugs. **Implementation of a rebate model and the resulting cash-on-hand reductions will draw down essential hospitals' inventory buffers and accelerate the risks of drug shortages.**

For products like CroFab antivenom—with a wholesale acquisition cost of $6,396 per unit—hospitals purchasing under a rebate model pay full cost up front and wait, potentially for months, until the product is used and a rebate is paid.[10] For the 59% of essential hospitals operating with less than two weeks of cash on hand, that float is not manageable.[11] With reduced inventory of emergency drugs, hospitals face a greater risk that critical therapies are unavailable when urgently needed. As more drugs enter the Medicare negotiation program, this harm will compound and provide inflationary pressure on pharmacy inventory spend.

Rebate Models Are Unnecessary to Implement the MDPNP

Drug manufacturers have claimed for years that rebate models are the only way to deduplicate 340B discounts from Medicare's maximum fair price (MFP).[12,13] That claim was always overstated, and it is now refuted by experience. Since the MDPNP took full effect on Jan. 1, 2026, covered entities, drug manufacturers, and the Department of Health and Human Services (HHS) have implemented tools that allow deduplication while preserving up-front discounts. Reversing course now would disrupt the deduplication infrastructure that is already working.

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[9] Swagel P. Letter to Ron Wyden, Frank Pallone Jr., and Richard Neal on June 4, 2025. https://www.cbo.gov/system/files/2025-06/Wyden-Pallone-Neal_Letter_6-4-25.pdf. Accessed April 6, 2026.
[10] Data Overview. Texas Department of State Health Services. https://www.dshs.texas.gov/prescription-drug-price-disclosure-program/data-overview. Accessed March 31, 2026.
[11] Centers for Medicare & Medicaid Services. Medicare Cost Reports (2024). Accessed March 31, 2026.
[12] Carpenter E, Stancel J. Letter to Thomas Engels on Sept. 8, 2025. https://cdn.aglty.io/phrma/global/resources/import/pdfs/Rebate%20Notice%20PhRMA%20Comments_FINAL.pdf. Accessed April 6, 2026.
[13] Novo Nordisk. 340B Program Policy Update. March 2, 2026. https://340besp.com/resources/novo_nordisk/policy.pdf. Accessed April 6, 2026.

Congress also made its intent clear when it designed the MFP: drug manufacturers must offer covered entities the *lower* of the 340B price or the MFP, expressly so the two programs would work in sync. More than 160 members of Congress reaffirmed this intent in September 2025, urging HRSA to abandon the rebate pilot and warning that "an unchecked rebate model would severely undermine" the 340B program's purpose. Most recently, a bipartisan group of members wrote to the House Appropriations Subcommittee on Labor, HHS, and Education in March 2026 urging inclusion of bill language to bar the use of any fiscal year 2027 funds to implement a 340B rebate model—explicitly on the grounds that HRSA's resources would be better directed toward protecting covered entities from actual and ongoing threats to the program.[14] **HRSA should not grant drug manufacturers a structural workaround that Congress has repeatedly declined to provide and explicitly declined to authorize with the MDPNP.**

a. HRSA's pursuit of rebate models is diverting attention from more pressing oversight failures.

While HRSA has devoted significant resources to developing a rebate model, drug manufacturers have been unilaterally imposing new claims submission requirements on covered entities that directly contravene the 340B statute. Eli Lilly and Novo Nordisk have both implemented onerous, divergent data submission requirements—conditioning access to 340B pricing on submission of detailed patient-level claims through proprietary platforms—without statutory authority to do so. These requirements impose real administrative burdens on covered entities today, yet HRSA has not moved to stop them.[15,16] The agency's continued focus on rebate model development while these abuses go unaddressed is precisely the misallocation of oversight resources against which Congress warned in its March 2026 appropriations letter.

b. HRSA's own precedent confirms rebates are warranted only to expand access, never to restrict it.

Since 1992, HRSA has authorized rebates in only one narrow context: AIDS Drug Assistance Programs (ADAPs). ADAPs lack a centralized distribution mechanism that makes up-front discounts operationally infeasible. That limited exception reflects a deliberate policy judgment by policymakers—**rebates exist to facilitate access to 340B pricing where up-front discounts cannot function, not as an alternative delivery mechanism for the program**. No comparable operational constraint exists for other covered entities. Expanding rebates beyond ADAPs would replace a targeted accommodation with a sweeping structural change.

c. The rebate model runs counter to the goals of the negotiation program by rewarding the most aggressive drug manufacturers.

It is unreasonable to require covered entities to pay more up front for the very drugs deemed most overpriced in the market. **These products were selected for the MDPNP precisely because their prices are excessive—so excessive that Congress took the**

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[14] Matsui D, Johnson D, Dingell D, et al. Letter to Robert Aderhold and Rosa Delora on March 27, 2026. https://image.email.aamc.org/lib/fe8e13727c63047f73/m/1/3fcab183-aee3-4029-b449-c04925307f27.pdf. Accessed April 15, 2026

[15] DeCubellis J. Letter to Thomas Engels on March 6, 2026. https://essentialhospitals.org/wp-content/uploads/2026/03/Novo-Nordisk-Claims-Submission-Letter.pdf. Accessed April 6, 2026.

[16] DeCubellis J. Letter to Thomas Engels on Jan. 29, 2026. https://essentialhospitals.org/wp-content/uploads/2026/01/Lilly-Claims-Data-Submission-obligations-letter.pdf. Accessed April 6, 2026.

unprecedented step of mandating federal price negotiation. A rebate model inverts that logic, forcing resource-constrained safety net providers to shoulder the highest up-front costs for the least affordable products, while drug manufacturers retain use of those funds during the rebate period.

If any reconciliation mechanism is needed, a more rational approach would require drug manufacturers to provide covered entities with access to the lower of the 340B ceiling price or the MFP at the point of sale, with any necessary adjustments occurring after the transaction. That structure would preserve statutory pricing protections without shifting financial risk onto providers. The proposed rebate model does the opposite and rewards drug manufacturers for excessive pricing while imposing additional financial strain on the safety net providers the 340B program is intended to support.

A "Pilot" is Not an Appropriate Vehicle for Fundamental Structural Changes

HRSA's framing of the rebate model as a limited "pilot" blatantly misstates its nature: a mandatory, nationwide, fundamental restructuring of how the 340B program works for every covered entity in the country, implemented on an accelerated timeline with no prior notice-and-comment process and no meaningful opportunity for covered entities to shape program design before being subjected to it. **A program applying to approximately 14,600 covered entities across 10 of the most widely used drugs in Medicare is a "pilot" in name only.**

a. The pilot was voluntary for drug manufacturers but mandatory for covered entities.

It is indefensible that participation in the rebate pilot will be optional for the parties that benefit from the rebate model and compulsory for the parties who are harmed by it. In the withdrawn pilot, once a drug manufacturer's plan was approved, every covered entity purchasing that drug was required to participate—with only two months' notice and before HRSA had responded to the more than 1,100 comments it received opposing the program. The pilot is a significant benefit to drug manufacturers, which gain both the float on hundreds of millions of dollars in up-front drug purchases and expanded claims data on covered entity purchasing patterns. **Covered entities receive none of these benefits and bear all the costs**. If HRSA moves forward with any version of a rebate pilot, participation must be voluntary for covered entities, not just for drug manufacturers.

b. Rebate models abdicate HRSA's statutory oversight role to private entities.

HRSA, not drug manufacturers, holds statutory authority to interpret and enforce 340B obligations. A rebate model that requires covered entities to submit claims data to drug manufacturer–operated platforms transfers core oversight functions to for-profit entities with a direct financial interest in limiting 340B utilization and claims approvals. This structure allows drug manufacturers to function as primary gatekeepers of the very discounts they are obligated to provide—determining unilaterally whether claims are approved, on what timeline, and under what documentation standards. **HRSA must recognize that delegating these authorities to drug manufacturers is an abdication of responsibility that Congress mandated to reside with HRSA.**

The 340B program statute specifically directs the Secretary to establish and implement an administrative process for the "resolution of claims by covered entities that they have been

overcharged for drugs purchased under this section, and claims by drug manufacturers, **after** the conduct of audits" (emphasis added).[17] 340B statute further clarifies that the imposition of sanctions of covered entities shall be determined by the secretary, clearly establishing that HRSA, not drug manufacturers, is responsible for evaluating program compliance.

The withdrawn pilot made this problem concrete. Every participating drug manufacturer selected Beacon Channel Management as its rebate platform. This positioned a single private vendor, accountable to drug manufacturers rather than HRSA or covered entities, at the center of a mandatory federal program. Beacon refused to complete standard data security questionnaires requested by covered entities seeking to comply with Health Insurance Portability and Accountability Act Security Rule requirements. This refusal raised serious questions about the protection of patient health information transmitted through the platform. Beacon's own FAQ indicated that rebate data would be integrated with its MFP platform and used to identify and reduce rebates in Medicare, Medicaid, and commercial channels—purposes well beyond the stated scope of the pilot and directly contrary to covered entities' interests. Meanwhile, Beacon made unilateral changes to claim validation requirements after program approval, with no HRSA authorization and no notice to covered entities.

These are not implementation details that can be fixed at the margins. They reflect what inevitably happens when a federal program's core functions are delegated to a private entity with financial ties to the parties it is supposed to hold accountable. **HRSA should not authorize any model that effectively delegates its own statutory role to the parties it is charged with overseeing.**

c. Any future rebate pilot must establish clear communication standards, operational safeguards, and a defined endpoint.

For a program of this magnitude, HRSA must be the authoritative source of program rules—not drug manufacturers or their vendor platforms. **Any changes to program requirements must go through HRSA review and be communicated to covered entities with adequate notice before taking effect.** Drug manufacturers and their designated platforms must be prohibited from making unilateral implementation changes. HHS has committed to "set any effective date for a new 340B rebate program to no earlier than 90 days following the public announcement of any approval of drug manufacturers applications."[18] **Any change to drug manufacturer plan implementation should undergo a similar review and approval timeline so covered entities have ample time to understand, provide feedback on, and implement the changes.**

HRSA must also include a system fail-safe that automatically reverts to up-front 340B discounts in the event of a platform outage. For many essential hospitals that operate with fewer than two weeks of cash on hand, even a brief delay in rebate payments can threaten operations, as the Change Healthcare cyberattack demonstrated.

Most fundamentally, HRSA must establish and publish clear criteria for evaluating a rebate pilot—including a defined end date—before implementation begins. The withdrawn pilot had no such criteria and no clear termination point: it was designed to run for "a minimum term of one calendar year," with expansion to additional drugs and drug manufacturers already signaled in

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[17] 42 U.S.C. § 256b (2024).

[18] *American Hospital Association et al. v. Kennedy et al.*, No. 2:25-cv-00600-LEW, PageID #: 1256 (D. Me. 2026)

HRSA's subsequent information collection request. A program with no defined endpoint, no published success metrics, and an explicit expansion trajectory is not a pilot. It is a permanent restructuring of the 340B program being implemented through administrative action rather than legislation.

That distinction matters enormously. The 340B program has operated on an up-front discount model for more than 30 years because that is how Congress designed it. Whether to fundamentally change that structure—shifting financial risk from drug manufacturers to covered entities on a program-wide and indefinite basis—is precisely the kind of major policy decision that should come from congressional action, not agency experimentation. The Supreme Court's major questions doctrine reinforces this point: agencies do not have implicit authority to make transformative changes to longstanding programs without clear congressional authorization. **If HRSA intends to make the rebate model a permanent feature of the 340B program, it should seek that authority from Congress—not manufacture it through an open-ended pilot with no exit.**

Responses to RFI Questions

RFI Section 1: Costs to Covered Entities

America's Essential Hospitals strongly **disagrees with HRSA's premise that it is possible to construct a rebate that will "cause minimal impact on 340B covered entities."[19]** Our members have already experienced irreparable economic harm due to the withdrawn rebate pilot and have provided us with firsthand estimates of previous and future financial damages brought by rebates. Rebate models would impose significant and ongoing operational, financial, and administrative burdens on safety net providers.

To quantify the costs of rebate models on essential hospitals, we used data from our members and information from HRSA to estimate the following direct costs of rebate models that would cause immediate financial harm:

- Staffing costs of hiring new pharmacy staff to implement the rebate model
- Technology costs for adapting existing systems to comply with new drug manufacturer requirements
- Legal fees for ensuring drug manufacturer compliance with the terms of the rebate program
- The costs of capital from floating funds to drug manufacturers while waiting for a rebate

In addition, we also modeled the following additional costs that hospitals are likely to incur based on the way HRSA designed its initial 340B rebate model pilot:

- The likely costs of drug manufacturer denials of 340B discounts, which are more likely under a 340B rebate model that puts drug manufacturers in control of determining whether covered entities can access statutorily required discounts
- The cost of stockpiled drugs that hospitals may not be able to get rebates for because, in the regular course of pharmacy operations, some drugs may expire before they are dispensed

[19] 91 Fed. Reg. 7287, 7288 (Feb. 17, 2026).

- The costs of subprime discounts that would likely be lost if 340B covered entities were required to purchase drugs at wholesale acquisition costs (WAC)

Overall, we estimate that **HRSA's proposed rebate pilot for MDPNP-covered drugs would cost hospitals approximately $3.7–$4.6 billion in 2027**. **If a rebate model expanded to additional drugs and drug manufacturers, we estimate annual costs of $10.2–$12.9 billion, which is nearly a quarter of the value of 340B savings for hospitals serving the safety net.**

In addition, we find that these costs would disproportionately harm essential hospitals. **Although essential hospitals account for 9% of 340B-eligible hospitals, they would incur 15% of the added costs.** This discrepancy is largely due to the higher volume of care that our members provide to low-income patients. Although the administrative costs are likely to be similar across hospitals, we find that essential hospitals will be more affected by disruptions to their cash flow and the potential risk of drug manufacturer denials of 340B discounts.

These costs alone should be reason enough for HRSA to reconsider proceeding with a rebate pilot program. However, if HRSA does move forward, the agency should develop a way to hold **drug manufacturers financially responsible for newfound costs that covered entities bear under a rebate model.**

For example, one approach would be to charge drug manufacturers a new administrative fee that HRSA would use to support and offset one-time and ongoing financial costs to covered entities. The fee could support costs associated with claims submission, information technology, and vendor costs. If a rebate pilot is authorized, HRSA should reevaluate the efficacy of the fee on a regular basis and rebate it as necessary to ensure that it adequately covers all costs of complying with the rebate pilot. **If HRSA does not feel that it has the authority or capacity to hold drug manufacturers responsible for the costs of implementing the rebate pilot, then it should not move forward with authorizing this model.**

CURRENT ADMINISTRATIVE COSTS UNDER THE UP-FRONT 340B DISCOUNT

Covered entities currently operate within a stable and well-established administrative framework that supports compliance with 340B requirements. Under existing policy, covered entities comply with requirements related to diversion prevention, duplicate discount controls, and audit readiness.

Essential hospitals currently process 340B-eligible drug transactions within longstanding pharmacy, billing, and compliance workflows. In most cases, 340B compliance activities are integrated into the responsibilities of existing pharmacy and finance staff rather than requiring standalone administrative infrastructure. The number of full-time equivalent (FTE) staff involved varies by hospital size and complexity and creates complex operational challenges, exacerbated by the accelerating complexity of drug manufacturer-mandated claims submission obligations. However, the up-front discount model is the most efficient means of effectuating 340B discounts.

Although drug manufacturers have increasingly imposed additional, non-statutory reporting requirements, the core structure of the program allows covered entities to maintain compliance with relatively limited staffing and without complex claims adjudication systems. **This**

structure enables hospitals to integrate compliance activities into routine operations without disrupting patient care.

Because the current up-front discount model makes discounts available at the point of purchase, the submission of claims documentation has a substantial effect on hospital cash flow. As a result, many of our members submit claims weekly or biweekly to meet operational and legal requirements without unnecessarily diverting resources from patient care.

ADMINISTRATIVE COSTS UNDER A POTENTIAL 340B REBATE MODEL PILOT PROGRAM

A rebate model would require covered entities to build entirely new administrative and operational infrastructure to access statutorily required 340B discounts. Hospitals would need to develop or procure systems to submit rebate claims after purchase, track claim status, reconcile payments across multiple drug manufacturers, and manage denials and appeals. These functions do not exist within the current 340B framework, which is designed around up-front discounts.

Our members identified three broad categories of direct administrative costs of the 340B rebate model pilot based on their experiences preparing for the initial pilot program:

- Staffing costs of hiring new pharmacy staff to implement the rebate model
- Technology costs for adapting existing systems to comply with new drug manufacturer requirements
- Legal fees for ensuring drug manufacturer compliance with the terms of the rebate program

Using data from our members and data from HRSA's own analysis, **we estimate implementing the rebate model for drugs included in the MDPNP would cost hospitals participating in the 340B program approximately $1.5 billion in direct administrative costs in 2027 alone.** Most of these costs are ongoing and likely will increase in future years. More details on our methods and assumptions for calculating these costs are described below.

HRSA must also consider how administrative costs could compound if additional drugs are added to the rebate program. If HRSA moves forward with upending more than 30 years of precedent in the 340B program, drug manufacturers likely will continue to push to expand rebate models to further profit. At a minimum, it is reasonable to assume that an implemented rebate program would continue to include drugs selected for the MDPNP, which are among the most frequently prescribed medications in the country.

In theory, if the process for submitting and monitoring rebates is similar across drug manufacturers, then covered entities may be able to achieve some economies of scale with new administrative costs. However, if drug manufacturers impose different requirements (as we have recently seen with new claims submission requirements by Eli Lilly and Novo Nordisk), then the costs will only continue to grow as new drug manufacturers are added. **Adopting more conservative assumptions, we estimate that if the rebate pilot were expanded to include all drugs and drug manufacturers, the direct administrative costs for hospitals would exceed $3.4 billion.**

STAFFING IMPACTS UNDER A POTENTIAL REBATE MODEL PILOT PROGRAM

Implementation of a rebate model would require both hiring new personnel and reallocating existing staff away from patient care and operational roles. Essential hospitals already operate

with more limited resources than other acute-care hospitals—including providing more charity care and treating more uninsured patients, despite their thin financial margins.

We estimated the direct administrative staffing costs of a rebate model by using HRSA's own estimates for the cost of labor needed to implement the rebate pilot and real-world data from our members about the staff that would have been required to administer this model.

In HRSA's ICR for its previous rebate model, the agency estimated that the pharmacy staff needed to implement a rebate model would cost $132 per hour, which was similar to estimates provided by our member hospitals. However, HRSA underestimated the implementation time required at only two hours a week.[20]

In their experience preparing to implement the rebate pilot, leaders from our member hospitals noted that they would need to hire at least one employee to work on this model full-time (40 hours a week). Many of our largest members have indicated that they would need to hire at least three FTE employees to manage the new process. These staff would be needed to conduct ongoing monitoring of claim determinations, investigate denials, and initiate formal appeals processes to ensure access to their statutorily required discounts.

Based on these data, we estimate that the rebate pilot would impose $1.2 billion in total direct staffing costs on all hospitals, including $135.9 million in costs on essential hospitals.

Even though HRSA has not yet implemented the rebate pilot program, it is important to note that our members are already experiencing economic harm from HRSA's haphazard and illegal attempts to implement rebates in the withdrawn pilot. For example, one member hospital has already allocated **approximately $300,000 in staff labor costs across affected departments to begin implementing a rebate program before it was stopped by federal courts.**

It is also important to note how staffing costs relate to the cash flow challenges a rebate model creates, which are discussed further below in response to Section 2 of the RFI. To mitigate the costs of fronting millions of dollars to drug manufacturers while they wait for rebates, several of our members have reported that they anticipate needing to perform daily claim submission through platforms such as 340B ESP, instead of the weekly or biweekly claim submission process they currently conduct under the existing model of up-front discounts. **HRSA's proposed rebate pilot program puts many essential hospitals in a lose-lose situation—they must spend more in staffing costs to prevent further losses from floating millions of dollars to drug manufacturers while they wait for rebates**.

SYSTEMS AND INFRASTRUCTURE FOR REBATE PILOT IMPLEMENTATION

Beyond staffing costs, a rebate model implementation would require significant investments in information technology systems and operational infrastructure. Existing 340B program systems are designed to manage drug purchasing and replenishment under an up-front discount framework. These systems are not designed to support the claims submission, adjudication, and payment tracking functions required under a rebate model.

Covered entities would be required to build or procure new systems to submit rebate claims, track claim status, reconcile payments across drug manufacturers, and manage denials and

[20] *American Hospital Association v. Kennedy*, No. 2:25-cv-00600-JAW, at 26. PageID #:1 (2025)

appeals. These functions are not part of the current 340B infrastructure and would require substantial system redesign. **Hospitals would need to modify billing, pharmacy, and revenue cycle systems to capture new data elements and establish claims-level reconciliation processes across multiple platforms.**

Hospitals also would need to ensure that any systems used to transmit rebate data comply with applicable privacy and security requirements, including protections for patient health information. Establishing secure interfaces between hospital systems and drug manufacturer-operated platforms would require additional technical safeguards, contractual protections, and ongoing monitoring. **During the withdrawn pilot, the Beacon platform refused to fulfill a security questionnaire one of our members requested, raising serious questions about vendor safety practices.**

These system changes would require substantial financial investment and development time. Hospitals likely would need to engage multiple vendors—including pharmacy management vendors, 340B compliance vendors, and revenue cycle vendors—to build and maintain these integrations. In many cases, vendor solutions would need to be customized for individual hospitals or health systems, further increasing implementation costs.

It is difficult to estimate the IT costs of implementing a new rebate pilot because technical specifications have not yet been determined. Hospitals have reported a wide range of costs, from $100,000 to $500,000 per hospital, to set up a new system, which do not include ongoing system maintenance expenses. Using data from our members, which suggest that IT costs would be approximately 15% of new staffing costs for the rebate pilot, **we estimate a total of $179.3 million in IT system costs for hospitals, in addition to the additive staffing costs in pharmacy and accounting departments for rebate compliance.**

OTHER ANTICIPATED COSTS OR IMPACTS OF A POTENTIAL 340B REBATE MODEL PILOT PROGRAM

In addition to the direct staffing and technology costs mentioned above, our members anticipate substantial legal expenses to ensure compliance with the new, administratively complicated rebate structure. Other potential costs that the RFI does not acknowledge include the costs of lost access to subprime discounts and the loss of up-front discounts on medicines that are stockpiled for emergencies but are not used prior to their expiration date in the normal course of pharmacy operations.

In response to Section 2 of the RFI, we provide more information about costs from the disruption in cash flow, and in response to Section 3 of the RFI, we provide more information about the likely cost of rebate denials.

Legal Expenses

The administrative complexity of the new proposed rebate models will require essential hospitals to incur additional legal fees to review rebate pilot terms and conditions and to assist with enforcing requirements that drug manufacturers pay essential hospitals the discounts required by statute. Although it is difficult to estimate these legal fees, data from our members suggest that these legal fees would be approximately 10% of the new staffing costs for the rebate pilot. As a result, **we estimate a total of $119.5 million in added legal fees for hospitals.**

Loss of Subprime Discounts

By requiring covered entities to purchase drugs at wholesale acquisition costs, many of our members will likely lose access to subprime discounts that they currently receive when they

purchase drugs for 340B-eligible patients. During the withdrawn pilot, drug manufacturers did not suggest they had plans to account for subprime discounts in their rebate payments to covered entities. While subprime discounts are not required by statute, HRSA should consider how upending longstanding policies and practices of the 340B Drug Discount Program will have ripple effects on other funding streams that essential hospitals rely on.

Although there is little public data available on subprime discounts, **we used data from our members to estimate that the rebate pilot program would result in approximately $83.6 million in added costs for hospitals losing access to subprime discounts.**

Additional Costs for Stockpiled Medicines

Requiring covered entities to purchase drugs at wholesale acquisition cost (WAC) creates an inflationary pressure on pharmacy inventory prices. CMS reports the products selected for the MDPNP in 2026 and 2027 at WAC cost more than $8 billion per month to Medicare Part D alone.[21][22] As covered entities currently purchase these products at a discounted price, **requiring them to purchase at a higher WAC will result in immense inflationary pressure, and force covered entity pharmacies to reduce inventory if keeping the same pharmacy spend.**

Maintaining surplus inventory is a key way essential hospitals mitigate the risk of shortages and triage economic shocks caused by extraneous factors. Raising up-front acquisition costs will directly reduce essential hospitals' ability to stockpile emergency medicines and to weather shortages such as those caused by Hurricane Helene's destruction of the Baxter North Cove Plant.

Rebate models will have further negative impacts on inventory operations. Over the course of regular pharmacy operations, some drugs that are purchased for patient care cannot be used before they expire. The 340B program's current up-front discount structure allows covered entities to receive discounts on these stockpiled drugs because they were purchased for use by 340B-eligible patients. However, under a rebate model, it is unclear if and how hospitals would be able to receive these statutorily required discounts.

Using data from our member hospitals for the drugs covered in the MDPNP, we estimate that approximately 2% of drug purchases may lose access to discounts because of the rebate pilot because they expire before use. Extrapolating these costs to all hospitals, **we estimate a total of $449.1 million in added costs to hospitals from lost access to discounts on stockpiled medicines.**

These costs are expected to grow if HRSA extends the rebate pilot to additional medicines that are not used as frequently. We are concerned that eliminating up-front discounts would affect essential hospitals' ability to stockpile medicines that are essential for emergencies but are rarely used. For products with long shelf lives but unpredictable demand, hospitals would be forced to tie up scarce capital for prolonged periods without assurance of timely reimbursement. **Over time, this will lead hospitals to reduce on-hand supplies of**

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[21] Fact Sheet: Negotiated Prices for Initial Price Applicability Year 2027. Centers for Medicare & Medicaid Services. https://www.cms.gov/files/document/fact-sheet-negotiated-prices-ipay-2027.pdf. Accessed April 6, 2026.

[22] Fact Sheet: Negotiated Prices for Initial Price Applicability Year 2026. Centers for Medicare & Medicaid Services. https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf. Accessed April 6, 2026.

these drugs, increasing the risk that critical therapies are unavailable when urgently needed.

RFI Section 2: Payment Timing and Potential Cash Flow Impacts for Covered Entities

A rebate model imposes a fundamental and inescapable cash flow burden on essential hospitals: from the moment a covered entity purchases a drug at WAC until the moment it receives the rebate, the hospital is financing the drug manufacturer's statutory discount obligation out of its own pocket. Pharmaceutical manufacturers have tried to obscure these costs by funding studies that minimize this reality through optimistic assumptions that do not reflect the operational reality facing essential hospitals. However, based on data from our members, **we anticipate that floating these costs to drug manufacturers could cost hospitals between $54.2 and $162.8 million, depending on the extent of their cash reserves.**

These costs will disproportionately harm essential hospitals because of the high volume of care our members provide to low-income patients and because of the pre-existing cash flow challenges many of our members face.

Industry-funded analyses minimize this burden by making a series of optimistic assumptions that do not reflect the operational reality facing safety net hospitals. When those assumptions are corrected, the cash float period extends to at least 30 days—and often longer—imposing costs that HRSA was required—but failed—to genuinely reckon with before the Maine court enjoined the pilot.

a. **Drug manufacturers incorrectly assume that hospitals can push costs to wholesalers.**

In December 2025, after hospitals challenged HRSA for not considering the costs of floating funds to pharmaceutical companies in its analysis of the effects of rebate models, the Pharmaceutical Research and Manufacturers of America (PhRMA) funded a report by IQVIA intended to minimize these legitimate cash flow concerns.[23] One primary flaw of this report is the assumption that hospitals could mitigate their cash flow concerns by delaying payments to wholesalers. This assumption does not reflect our members' real-world experience and ignores the way rebate models would disrupt the processes that essential hospitals use to purchase medicines their patients need.

The IQVIA study mistakenly argues that cash flow challenges start when a drug is dispensed to the patient, but a hospital's cash exposure begins much earlier, when the hospital purchases drugs from the wholesaler. **Overall, we anticipate that hospitals will have to float funds for at least one month in even the most optimistic scenario.** This estimate is supported by the IQVIA analysis, which assumes that a hospital purchases a drug at WAC 15 days before dispensing, submits claims data five days after dispensing, and—if everything goes perfectly—receives the rebate 10 days later (day 15). **If drug manufacturers experience any processing delays, or if covered entities' submissions require any back-and-forth—a near certainty during the initial period of a new and untested data platform—that window extends further.**

[23] How Will a Rebate Model Impact Cash Flow in the 340B Drug Pricing Program? IQVIA. https://www.iqvia.com/locations/united-states/library/fact-sheets/how-will-a-rebate-model-impact-cash-flow-in-the-340b-drug-pricing-program. Accessed April 6, 2026.

b. Cash flow impact is meaningfully different under a rebate model than under existing inventory models.

Most 340B hospitals currently use a replenishment drug inventory model. Under this model, the hospital purchases a package of a drug at the drug's commercial price. Once the entire package has been dispensed for 340B-eligible scripts, the hospital replenishes its stock by repurchasing a package at the 340B price going forward. Where hospitals use contract pharmacies, 340B providers are never asked to pay the full commercial price for filling eligible prescriptions; they only pay the 340B discounted price.

Proponents of a rebate model have claimed that there is no difference between a rebate model and the replenishment model. That is not true. **Under the replenishment model, covered entities pay the full commercial price for a drug *no more than once*. But under a rebate model, covered entities would have to pay the full commercial price *every time* they make a purchase.** The D.C. district court has explicitly highlighted this difference and explained that "[b]efore a rebate is received, covered providers would effectively float manufacturers the 340B discount value."[24] A dramatic increase in the up-front cost of repurchasing 340B drugs is not an insignificant risk for providers operating with limited days' cash on hand and the chances for improperly denied or delayed rebates raise the stakes even higher.

c. Rebate models provide an interest-free loan to drug manufacturers at the expense of safety net providers.

Even assuming prompt rebate payments and minimal administrative burden, the required cash flow transfer from covered entities to drug manufacturers creates significant financial harm. These costs will be higher for essential hospitals and other covered entities with existing cash flow challenges.

For hospitals with adequate cash on hand, we estimate the costs of floating funds to pharmaceutical manufacturers would be equal to average interest rates on funds, which the IQVIA study estimates to be 4–5%. **In our optimistic scenario, we assumed a 4% interest rate, which would still result in $54.2 million in costs for hospitals for a 340B drug pilot. These costs would grow proportionally if the rebate were extended to all drugs, likely exceeding $155 million a year.**

Unfortunately, many essential hospitals cannot afford the added costs of fronting funds to drug manufacturers and might need to take out loans to cover the costs of these payments. **Using estimates for the cost of these loans from the IQVIA study, we estimate that the interest rate on these loans could be 12%, which would translate to $162.8 million in interest costs for all hospitals for the 340B rebate pilot.**

These costs will only grow as the number of drugs in the rebate pilot continues to grow. Unlike administrative costs, there are no potential economies of scale. Overall, **if a rebate model were extended to all 340B drugs, we estimate that the financing costs to hospitals would be at least $155–$465 million.**

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[24] *American Hospital Association et al. v. Kennedy*, No. 1:24-cv-03220-DLF, Document 54 (D.D.C. 2025).

d. Restricting cash flow will threaten broader financing and bond covenants structures.

For safety net hospitals operating with limited cash reserves, **this financing requirement would reduce available cash on hand and restrict financial flexibility.** The lost interest revenue is only a fraction of the irreparable damage. For example, reduced liquidity could affect compliance with bond covenants, credit ratings, and the ability to finance future capital investments such as facility upgrades, service expansions, or technology modernization. **Requiring hospitals already operating under severe financial pressure to finance drug purchases on behalf of drug manufacturers could have serious long-term consequences for their ability to sustain services.**

The amount of funding that essential hospitals would need to float to drug manufacturers will materially affect their already low operating margins. For example, **one of our members projected that the total amount of funds that they would have needed to float to drug manufacturers under the initially proposed rebate pilot would be 11.4% of their net patient operating revenues.** The hospital already operates with a negative operating margin, and so it is not sustainable to further constrict the funds available to support the essential services they provide.

e. If HRSA insists upon a rebate model, it should use the shortest prompt payment window possible with deadlines for claims adjudication.

We appreciate that HRSA asked about modifying the previously proposed 10-day window to mitigate cash flow concerns for covered entities, and we urge HRSA to use the shortest window possible. However, to be effective, HRSA must also ensure that there are deadlines for manufacturers to adjudicate any claims that are processed incorrectly.

Because hospitals must put up funds to purchase drugs before they are dispensed to patients, an up-front discount is the best way to make sure that 340B discounts are paid in a timely manner. **One option for HRSA's consideration would be to provide covered entities with a presumptive rebate equal to at least one month of claims that would then be reconciled after the drug is dispensed.**

f. HRSA should develop policies for drug manufacturers to mitigate cashflow concerns for resource-constrained hospitals.

As emphasized throughout this letter, if a rebate model is implemented, our member hospitals would face legitimate cashflow issues. **Any rebate model should include a process established by HRSA through which drug manufacturers must mitigate detrimental cash flow disruptions for resource-constrained hospitals.**

For example, CMS recognized this need in developing the MDPNP. Entities may self-identify as anticipating material cashflow concerns because of payment delays stemming from retrospective MFP refunds. Drug manufacturers must include in their effectuation plans a description of "their approach to mitigating material cashflow concerns, including establishing criteria for dispensing entities to participate in their approach."[25] In CMS' MDPNP guidance,

[25] Centers for Medicare & Medicaid Services. Medicare Drug Price Negotiation Program: Final Guidance. Sept. 30, 2025. https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf. Accessed April 6, 2026.

the agency also provides examples of such mitigation processes including a prospective purchasing agreement or accelerated MFP refund timelines. HRSA should go further to identify which hospitals will face cashflow issues due to the rebate model and mandate that drug manufacturers take particular actions, such as an accelerated refund timeline, to mitigate such concerns.

RFI Section 3: Rebate Denials

Rebate denial risk is among the most serious operational concerns associated with a rebate model. We appreciate that the withdrawn rebate pilot included guardrails to prohibit covered entities from denying rebates due to suspicion of diversion or discount duplication and **we urge HRSA to restrict the reasons that rebates can be denied to the narrow circumstances specified within the withdrawn pilot.**

However, under the withdrawn rebate pilot, drug manufacturers still retained broad discretion to review and deny rebate claims submitted by covered entities. Without clear dictated standards governing these decisions, drug manufacturers could effectively determine whether a covered entity receives the statutory 340B price. Based on prior experience with drug manufacturers and insurers, we still expect that a portion of legitimate claims will be denied. Assuming a 10–15% denial rate, which is consistent with our members' experience with other payers, **we estimate the costs of denials for hospitals could be approximately $1.6–$2.4 billion for MDPNP drugs and $4.7–7.0 billion across all 340B covered drugs.**

Our members also expect to incur additional costs when drug manufacturers misidentify 340B claims. Under the current up-front discount policy, a covered entity retains the discount for an alleged mistake while the dispute is resolved, protecting covered entities from incorrect determinations made by a drug manufacturer. However, a rebate model reverses this framework by allowing drug manufacturers or their designees to deny a rebate at any stage. As a result, the penalty for an incorrect determination is borne immediately by the covered entity, and reprieve can only be granted after permanent economic harm has already been suffered.

To mitigate these costs, HRSA should add additional guardrails and avoid abdicating its oversight authority to drug manufacturers who frequently impose additional administrative burdens on providers without adequate justification.

a. **HRSA should articulate the narrow grounds under which drug manufacturers may deny rebates.**

In the withdrawn pilot, HRSA took an important step to prohibit drug manufacturers from denying 340B rebates based on compliance concerns with diversion or Medicaid duplicate discounts. **We appreciate these prior clarifications from HRSA**; however, the agency did not provide an exclusive list of the grounds for which denials would be permitted.

In any final version of a rebate model, **HRSA should explicitly detail the narrow circumstances under which a drug manufacturer can deny a claim. 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 drug manufacturer denies a claim for one of these reasons, a covered entity should be allowed to correct the claim and resubmit it.

b. HRSA should specify standardized documentation and timeline requirements.

Drug manufacturers set to participate in the withdrawn pilot established differing processes that covered entities should take to rectify denials due to certain issues (e.g., missing fields, multiple covered entities submitting the same claims). In any future rebate model, the process for disputing the same types of denials should be standardized across drug manufacturers, including uniform required documentation.

HRSA also should set a timeline for rectifying improper denials. In the withdrawn pilot, covered entities were instructed to communicate first with the claims IT platform, next with the drug manufacturer, and only then with HRSA, via a generic 340B email address. Additionally, some drug manufacturers were instructing covered entities to rectify denials amongst themselves. Such processes can be lengthy, and the IT platform and drug manufacturers will not be motivated to rectify improper denials swiftly. **HRSA should set a requirement for the number of days a drug manufacturer has to resolve a disputed denial.**

c. HRSA must ensure prompt and uniform dispute resolution.

If a rebate model is implemented, HRSA must include strong guardrails to ensure disputed claims are promptly handled, including the use of civil monetary penalties (CMPs) where appropriate. We are deeply worried that the withdrawn pilot had no timeline for claims dispute resolution. **A prompt determination policy is useless if denied claims enter an indeterminate limbo period.**

As part of the withdrawn pilot, drug manufacturers' letters to covered entities include 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 drug manufacturer stated that the covered entities must resolve that issue with each other, while another drug manufacturer stated that it will only recognize the first submitted claim. **The process for disputing the same types of denials should be standardized across drug manufacturers.**

Additionally, if a covered entity cannot resolve an issue with the IT platform or drug 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 also has 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.**

d. HRSA should enforce prompt payment through clear penalties, including CMPs.

Under federal law, HRSA holds the statutory duty to ensure that obligated discounts are provided to 340B covered entities.[26] Any drug 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."[27]

In an instance where an obligated rebate claim is left unpaid, and a covered entity is unable to realize a 340B discount, a drug 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 drug manufacturer malfeasance, HRSA should levy CMPs on the responsible party. **HRSA should clearly articulate the specific circumstances under which CMPs may be levied and how they will be enforced.**

e. **Noncompliant drug manufacturers that are unable to promptly effectuate rebates should be removed from the program.**

In the withdrawn pilot, HRSA appropriately determined that drug manufacturers that do not comply with program requirements could be removed from the rebate pilot program. However, HRSA improperly failed to clarify under what circumstances a drug manufacturer would be found to be out of compliance with program requirements. **The standard articulated for the withdrawn pilot was that if a drug manufacturer "trends toward. . .not paying rebates within 10 days of data submissions" they could be removed. This vague standard is completely inadequate. HRSA should instead strictly require that all drug manufacturers abide by the established window for claims payment.**

RFI Section 4: Data Collection by Covered Entities

Covered entities already maintain significant data systems to support compliance with the 340B program. These systems are designed to support and engage with myriad key responsibilities, including HRSA audits, diversion prevention, duplicate discount prevention, and contract pharmacy oversight.

The data collection envisioned under a rebate model would expand these requirements substantially. In particular, the rebate pilot would require covered entities to submit claims-level information to drug manufacturer–designated platforms, potentially including sensitive patient data.

HRSA must ensure that any such systems comply with all federal privacy requirements and provide adequate safeguards for protected health information. Covered entities are also concerned that manufacturers might seek to use rebate data for purposes unrelated to the rebate program, including efforts to target contract pharmacy arrangements or initiate compliance investigations. **HRSA should explicitly prohibit drug manufacturers from using rebate data for purposes outside the administration of the rebate model.**

a. **HRSA must validate rebate platform's methodology and protection of personal health information (PHI).**

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[26] 42 C.F.R. § 10.10 (2025).
[27] Ibid.

As the agency designated by the statute of the 340B Program to house OPA, HRSA is obligated to monitor drug manufacturer compliance with 340B program requirements. Throughout the duration of implementation for the withdrawn rebate pilot, HRSA never publicly communicated details regarding PHI protection standards for rebate platforms like Beacon. If HRSA pursues another rebate model, any implicated information technology platform must meet the same program compliance standards as HRSA. **IT platforms participating in a rebate pilot must conform to all legal requirements regarding receiving, holding, and transmitting any PHI.**

b. HRSA must ensure that data provided to drug manufacturers or drug manufacturer–selected platforms are not used for purposes outside the rebate model, including audits or targeting of contract pharmacies.

We were deeply disappointed by HRSA's decision to expand the slate of permissible claim fields—beyond the initial pharmacy claim fields outlined in the original rebate notice—and fear drug manufacturers seek to erode protections HRSA has previously put in place to protect 340B covered entities. Drug manufacturers have a documented history of misusing data to restrict covered entity access to 340B discounts, while HRSA has a duty to safeguard PHI and maintain program integrity.

The Beacon Platform, selected by every single drug manufacturer for the withdrawn rebate pilot, continues to state on its FAQ page, "340B rebate data created in Beacon Rebate Model is integrated with Beacon MFP in order to account for duplication in MFP and 340B rebates."[28] Even more troublesome 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."

RFI Section 5: Drug Manufacturer Efforts to Avoid Duplicate Discounts

a. Rebate models are not necessary to deduplicate MFP claims.

As HRSA has stated, there are viable alternatives available for drug manufacturers to address 340B and MFP deduplication other than rebates.[29] **HRSA and CMS should work together to implement alternative deduplication methodologies that do not undermine the 340B program.**

For example, CMS has indicated that it is launching a voluntary 340B claims repository this year, which it might use in the future to exclude 340B drugs when determining Medicare Part D inflation rebates.[30] We applaud CMS for testing the repository and implementing user and industry feedback before making further decisions on the repository's future. Investing in the repository is a helpful alternative to individual drug manufacturer requirements when addressing MFP/340B deduplication issues while protecting access to 340B discounts and limiting provider burden.[31]

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[28] Rebate Model Frequently Asked Questions. Beacon Support Center. https://www.hrsa.gov/. Accessed April 6, 2026.
[29] *American Hospital Association, et al. v. Kennedy, et al*, No. 25-2236 Motion of Defendants-Appellants at 13, (D.C. Cir. Dec. 30, 2025).
[30] 90 Fed. Reg. 49741 (Nov. 5, 2025).
[31] Siegel B. Letter to Mehmet Oz on Sept. 12, 2025. https://essentialhospitals.org/wp-content/uploads/2025/09/CY2026-PFS-9.12.25.pdf. Accessed April 6, 2026.

RFI Section 6: Required Reporting

a. HRSA should monitor drug manufacturers' payment timelines, rate of denials, and denial dispute timeline.

HRSA should collect information on the number of days it takes for drug manufacturers to provide a rebate, the number and percentage of claims that are denied, and the number of days it takes for a claim dispute to be resolved. This information should be aggregated and published on HRSA's website regularly.

b. HRSA should publish manufacturers' rebate plans

Drug manufacturers' fully approved rebate plans should be published on the HRSA website for public viewing. During the withdrawn rebate pilot, the agency only posted a "summary" of the approved rebate model plans on its website. Merely publishing a summary of drug manufacturers' plans does not go far enough; the full plans as approved should be available for public review. Publishing the full plans will enable covered entities to provide immediate feedback to HRSA if programmatic details in drug 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 drug manufacturer plans.

It is critical that HRSA preemptively publish stakeholder plans to ensure all covered entities can fully review their potential obligations under a rebate model. Sharing versions of submitted plans upon request delays the transparency and oversight needed to hold drug manufacturers accountable.

RFI Section 7: 340B Program Integrity and Other Potential Benefits of a Rebate Pilot

a. HRSA's focus on rebate models detracts from actual protection of the 340B program and covered entities.

HRSA describes its purpose as "to improve health outcomes through access to quality services, a skilled health workforce, and innovative, high-value programs." In the reckless pursuit of 340B rebates, however, the agency has failed to respond to actual and current threats to the 340B program.[32] In the more than 18 months since drug manufacturers first tried to implement rebates, drug manufacturers have continued to undermine the 340B program.

Eli Lilly and Novo Nordisk have implemented onerous, divergent, and dangerous 340B claims submission requirements that directly contravene 340B statute. Drug manufacturers increasingly are conditioning access to 340B pricing on submission of detailed claims and patient-level data through proprietary platforms, effectively rewriting program requirements outside of statute or regulation. **America's Essential Hospitals has written to HRSA on each of these drug manufacturers' policies and has yet to receive substantive response.**

[32] About HRSA. Health Resources and Services Administration. https://www.hrsa.gov/about. Accessed April 6, 2026.

HRSA's own audit program has repeatedly identified drug manufacturer overcharges and compliance failures requiring repayment to covered entities. For example, HRSA audits have found drug manufacturers charging above the 340B ceiling price and failing to provide required refunds, resulting in mandated repayments and corrective action plans.[33] Despite these ongoing compliance issues, enforcement remains limited, and these risks to covered entities persist while HRSA continues to prioritize development of rebate models that are unnecessary for the reasons the agency itself established.

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Rebate models represent an existential threat to the capacity of essential hospitals to provide care that their communities rely on. **We urge HRSA to weigh the demonstrated harm of rebate models and to reject such dramatic changes to the 340B program for the sake of patients who depend on essential hospitals for the care they need.**

America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Director of Policy Robert Nelb, MPH, at 202-585-0127 or rnelb@essentialhospitals.org.

Sincerely,

Jennifer DeCubellis
President and CEO
America's Essential Hospitals

[33] *FY 2025 Manufacturer Audit Results.* Health Resources and Services Administration. https://www.hrsa.gov/opa/program-integrity/fy-25-manufacturer-audit-results. Dec. 18, 2025. Accessed April 15, 2026.