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August 27, 2025

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

Re: Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14998)

Dear Administrator Engels:

On behalf of our more than 2,000 member hospitals and health systems that participate in the 340B Drug Pricing Program, the American Hospital Association (AHA) appreciates the opportunity to comment on the Health Resources and Services Administration's (HRSA) notice of the 340B Rebate Model Pilot Program. The AHA has serious concerns with *any* adoption of a rebate model, including through the proposed pilot program. For three decades, the upfront discount model has performed well and expanded access to care for millions of Americans. But as the agency recognized in its Notice, any approval of a rebate model will "fundamentally shift how the 340B program has operated for over 30 years." There is no sound reason for HRSA to make such a profound change. Sections 2 and 3 below explain why.

But with applications due on September 15 and approvals set to be announced a month later on October 15, it seems clear that the agency is committed to pursuing this pilot program. Although we wish that the agency would not go down this path, we are confident that what it calls a "test" will ultimately fail. In the meantime, however, it is critical that the pilot program do as little harm as possible to hospitals, patients, and communities during this one-year experiment. Accordingly, the AHA begins this comment letter by explaining the bare minimum requirements for this pilot program to operate fairly and effectively.

Simply put, the pilot program must contain crystal clear guardrails — accompanied by robust enforcement mechanisms — to ensure that drug companies do not abuse it. HRSA's recently posted "Frequently Asked Questions" page is a positive first step in this regard. But it is not enough. Time and again, drug companies have demonstrated

that they will evade 340B rules and regulations to pursue their own financial benefit — especially when there is even a speck of ambiguity in the agency's requirements (and often when there is none). The drug companies will push those ambiguities past the breaking point, exploiting any small bit of doubt, real or invented, to their own advantage and to the 340B Program's detriment. HRSA must account for that historic misbehavior and impose additional safeguards to mitigate adverse impacts for hospitals and health systems.

Ultimately, HRSA should abandon this rebate model pilot program. It is a "solution" in search of a problem. More accurately, it is a "solution" that will create a host of problems for those who provide care for rural and other underserved Americans. But given the agency's apparent interest in forging ahead, **HRSA must impose stronger, inescapable safeguards — including a method to ensure that drug companies pay for the *full range of costs* and administrative burdens associated with a rebate model. And it must incorporate strict enforcement mechanisms to address drug companies' inevitable non-compliance.**

Department of Health and Human Services Secretary Kennedy has rightly recognized that "if there's no penalty," then drug companies will engage in "serial" misbehavior.[1] HRSA must not allow that to happen here.

I. ADDITIONAL REQUIREMENTS ARE NEEDED FOR 340B REBATE MODEL PILOT PROGRAM

The AHA appreciates HRSA's efforts to limit the scope of the pilot program and to impose "General Requirements" on the drug companies that choose to participate in it. We also appreciate HRSA's recognition that "additional safeguards" may be needed. To that end, the AHA urges the agency to provide greater clarity and make several changes to the safeguards announced in its Notice to mitigate some of the adverse impacts of the rebate model. We respectfully ask the agency to:

1. **Require drug companies to cover the *full range of costs* associated with a rebate model.** The Notice states that the plans submitted by drug companies "should include assurances that all costs for data submission through an Information Technology (IT) platform be borne by the manufacturer and no additional administrative costs of running the rebate model shall be passed onto the covered entities." We appreciate the agency's inclusion of this requirement in its Notice.

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[1] *See* Lex Fridman Podcast #388, Transcript for Robert F. Kennedy Jr: CIA, Power, Corruption, War, Freedom, and Meaning (July 6, 2023), *at* https://lexfridman.com/robert-f-kennedy-jr-transcript/.

But data submission costs are only one small part of the costs hospitals will be forced to bear under a rebate model. Hospitals will need to hire additional staff, pay their 340B third-party administrators (TPA) to manage data flows across multiple drug dispensing channels and foot potential legal costs associated with improper rebate delays or denials. Critically, they will now need to operate under two systems: one for drugs included in the pilot program, and one for all other drugs. Many hospitals and health systems — especially in rural and other underserved areas — cannot bear these added costs in this financial environment. For many, those costs will outweigh the value of participation in the 340B program. That cannot be what Congress or the agency intended.

So if HRSA truly wants to ensure that "no additional administrative costs of running the rebate model are passed onto covered entities," then it should clarify that this involves drug companies reimbursing *all of these additional costs*. Put another way, no additional administrative costs must mean no additional administrative costs — of any kind. And as with all features of this rebate model program, the agency must ensure that the drug companies actually pay these costs in a timely manner. The AHA is willing to work with HRSA to identify ways this could be operationalized, such as asking hospitals to submit budgets to HRSA in advance or invoices directly to drug companies, detailing the costs they will incur with a rebate model. **But before the agency moves forward with approval of drug company applications, it must make certain that the applicants are willing to bear *all of the costs* that hospitals and health systems will incur.**

2. **<u>Establish strict enforcement guidelines for drug company non-compliance</u>.** The Notice provides for only the following enforcement measure: revocation of a drug company's rebate model application if they are non-compliant with the pilot program's requirements. While significant and welcome, this does not go far enough to penalize a drug company for violating the program's requirements, particularly when the rebate model has such critical implications for 340B hospitals. HRSA should exercise its authority under (d)(1)(B)(vi) of the 340B statute and impose civil monetary penalties (CMP) for each instance of non-compliance (*e.g.*, an improper rebate denial, delayed rebate payment, failure to pay for hospital costs and administrative burdens associated with the pilot program). The relevant acts of non-compliance here constitute statutory overcharges, and so they should be penalized accordingly. And using its statutory oversight authority under 42 U.S.C. 256(d)(1)(B)(ii)(II), the agency should require drug companies to pay interest on any failure to rebate covered entities after the required 10 days.

In addition, the Notice makes no mention of *how* HRSA will determine non-compliance or how many instances of non-compliance lead to a penalty. Again, the AHA appreciates that the agency has tried to provide further clarification in its FAQ webpage by stating: "If a claim takes longer than 10 days

for a rebate to be paid, covered entities and manufacturers should work to resolve the issue. If a manufacturers trends toward not paying rebates within 10 days of data submissions, OPA reserves the right to revoke the rebate model approval for that manufacturer." This answer, unfortunately, does not provide the necessary clarity.

The AHA is extremely skeptical that the drug companies, whose profits improve when rebates are delayed or denied, will work in good faith to resolve disputes with hospitals and health systems over the timeliness of rebate payments.[2] And it is unclear what the agency means by "trends toward" failing to pay, or how or when it will determine whether to revoke the rebate model approval for a given manufacturer. Given what is at stake for hospitals, patients, and the 340B Program itself by this unprecedented allowance of a rebate model, HRSA should not take a permissive attitude toward non-compliance. Nor should it give drug companies this undefined "trend-toward" berth to violate the rules.

These important clarifications must be added to the agency's Notice or FAQ.

3. **Establish a centralized platform for data submissions that are managed by HRSA or a neutral, third-party entity.** The current framework allows each drug company to establish its own process for making the 340B price available under the rebate model. Despite the guardrails provided, each drug company has been given the latitude to use its own IT platform and require a different set of data elements to submit for a rebate. As a result, hospitals will have to manage many different rebate model schemes. (This adds to the costs discussed above in #1 that must be covered by the drug companies.) In fact, even with the list of 10 Medicare Part D drugs that are included in the pilot program, there are 9 different drug companies that could have 9 different rebate models with 9 different IT platforms that hospitals would need to submit data to receive a rebate. We cannot overstate the complexity and administrative burden this will introduce. This is the exact kind of unnecessary and inefficient variation in the health care system that contributes to an estimated 30% of all health care spending going toward administration instead of patient care.[3]

   Moreover, under the current framework, hospitals would submit data to IT platforms that are either directly owned by drug companies or by third parties that work closely with drug companies. Certainly, these IT platforms will not be neutral parties. We are concerned about the risk of conflicts of interest or

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[2] *See* Lex Fridman Podcast #388, Transcript for Robert F. Kennedy Jr: CIA, Power, Corruption, War, Freedom, and Meaning (July 6, 2023), *at* https://lexfridman.com/robert-f-kennedy-jr-transcript/ ("I think it was Upton Sinclair, that it's very difficult to persuade a man of a fact if the existence of that fact will diminish his salary.").

[3] https://www.commonwealthfund.org/publications/issue-briefs/2023/oct/high-us-health-care-spending-where-is-it-all-going

improper use of the data for purposes *outside* the scope of this rebate model pilot program.

For example, one of the IT platforms that will be used by some of the drug companies — Beacon by Second Sight Solutions — is a wholly owned subsidiary of the Berkeley Research Group (BRG), which is a consulting firm that has a long history of working for drug companies and their trade association, PhRMA.[4] In fact, BRG has released a number of reports funded by PhRMA and critical of the 340B program.[5] In addition, Second Sight Solutions is also the parent company of 340B ESP, the IT platform of choice for several drug companies that have imposed unlawful 340B contract pharmacy restrictions.[6] This is simply another way of allowing the fox to guard the henhouse. At the very least, HRSA should impose strict guidelines on how information may be used — specifically, only in connection with the limited pilot program. And again, it should strictly penalize drug companies if information is used for any other purpose.

To most effectively remedy these concerns, HRSA should identify and engage a single neutral, third-party entity to serve as a clearinghouse for any data submissions required under the agency's rebate model. In fact, the agency need not look far for a potential solution like this. In the CY 2026 Physician Fee Schedule rule, the Centers for Medicare & Medicaid Services (CMS) proposed to pilot a 340B claims data repository for use in identifying 340B units for the calculation of Medicare inflation rebates required under the Inflation Reduction Act (IRA).[7] **HRSA could use this same repository for the rebate model pilot program.** This would (1) minimize some of the administrative burden associated with the rebate model by allowing hospitals to submit claims data to a single entity; (2) limit the ability of drug companies to use any data for reasons outside the scope of this rebate model; and (3) allow the agency to more easily oversee the pilot program.

4. **Create a dedicated process to resolve rebate disputes.** The notice states that covered entities can "raise concerns with the Office of Pharmacy Affairs (OPA) if there are issues with rebate delays and denials, or any other administrative or logistical issues emerging through implementation of the rebate model." But the agency does not specify how it expects 340B hospitals to raise these concerns or provide for a particular process to facilitate that beyond providing a general email address to lodge complaints. This is dangerously insufficient given the implications of the rebate model on hospital finances.

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[4] https://beaconchannelmanagement.com/
[5] https://media.thinkbrg.com/wp-content/uploads/2024/05/13163125/340BProgram_Relative_Size_WP_2022Update.pdf
[6] https://www.340besp.com/
[7] https://www.federalregister.gov/documents/2025/07/16/2025-13271/medicare-and-medicaid-programs-cy-2026-payment-policies-under-the-physician-fee-schedule-and-other

If the agency expects hospitals to raise any concerns through the existing 340B Administrative Dispute Resolution (ADR) process, this process will not suffice. Even if rebate delays and denials are considered to be overcharges (and they are), we are concerned that statutory limits could preclude ADR review of any issues related to administrative or logistical issues with the rebate model. Moreover, the ADR process can take up to one year before a decision is rendered, which would mean that hospitals would have to forgo a rebate and float large sums of cash for an extended period — much longer than the 10 days allowed under the agency's notice. **Therefore, we strongly recommend that HRSA create a separate process to collect, respond to, and adjudicate any disputes related to its rebate model pilot program**.

This separate process should allow for expedited review and timely decisions of any rebate-related claim disputes. **Most important, the agency should provide (1) a designated human point-of-contact to receive complaints (and follow-ups on those complaints) and (2) a specific timeline for when those complaints will be addressed.** HRSA should take these extra measures to ensure that 340B hospitals have an accessible and timely mechanism to raise concerns and resolve rebate-related disputes.

5. **Denial documentation must provide a thorough explanation for why a rebate will not be paid.** The AHA hopes that there will be a small number of rebate denials, especially since drug companies may *not* deny rebates based on program integrity concerns. But we also recognize who we are dealing with here: drug companies that have consistently and creatively developed ways to evade the rules of the 340B program. Thus, it is not enough for the agency to state in its Notice that drug companies must provide "documentation in support" of a denial. Any denial documentation must include: 1) a narrative description of why a rebate claim is being denied, and not just a conclusory statement like the one included in the Notice ("deduplication for MFP or 340B provided to another covered entity on the same claim); 2) supporting primary source materials (*e.g.*, claims information, indication of which other covered entity received a rebate) justifying such a denial; and 3) a signature or attestation by a drug company employee, along with their telephone number or email address, so that covered entities can reach them to address any incorrect denials. In fact, HRSA should also consider creating a standard denial form to streamline the administrative process and provide covered entities with sufficient information to understand (and potentially challenge) a denial.

6. **Clarify that drug companies cannot deny rebates based on unilateral contract pharmacy restrictions.** While we appreciate the agency noting that drug companies must ensure that "340B rebates are not denied based on compliance concerns with diversion or Medicaid duplicate discounts," the agency does not address whether drug companies can deny 340B rebates for contract

pharmacy claims subject to drug companies' own unlawful and unilateral contract pharmacy restrictions. As HRSA knows, since 2020 dozens of drug companies have imposed restrictions on access to 340B discounted pricing through contract pharmacies. These restrictions have created enormous administrative and financial burdens for 340B hospitals nationwide.[8] If drug companies are allowed to deny rebates for contract pharmacy claims that ignore these unilaterally imposed restrictions, it will compound the harm these restrictions have already caused 340B hospitals. Therefore, HRSA should clarify that drug companies are not allowed to use these contract pharmacy restrictions as a backdoor way to deny 340B rebates under this pilot program.

7. **Define how the agency will measure and determine success of the pilot program.** HRSA's stated goal of the pilot program is to "better understand the merits and shortcomings of the rebate model." But the agency does not specify how it will achieve this goal or how it will determine whether the pilot program was successful. Perhaps this is because, as explained below, the agency does not clearly explain why it is opening the door to rebate models in the first place. *See infra* at 8. Either way, this failure to define success is particularly concerning because the agency indicates a successful pilot could result in expansion of the rebate model to more 340B drugs.

   At a minimum, HRSA should be transparent about the criteria it plans to use to assess the "success" of the pilot program. The Notice states that the agency will collect information from drug companies regarding delays and denials, but the agency does not specify how it will determine an *acceptable* level of claim delays or denials. Given the costs and administrative burdens even a single delay or denial will impose on 340B hospitals, we believe that any improper delays or denials should be weighted heavily by the agency in determining the "success" of the pilot program.

   The agency also does not include any measures of benefits that the rebate model purportedly will bring. If the rebate model is working nearly as well as the preexisting upfront discount model, but the new rebate model carries additional costs and upsets established reliance interests, there is no reason to expand it beyond this one-year pilot.

   Finally, since a rebate model will likely reduce the number of 340B drug purchases and thereby the discounts drug companies are providing, HRSA should include in its evaluation of the pilot program whether drug companies are reducing their prices to reflect the fewer 340B discounts they are providing.

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[8] https://www.aha.org/2022-11-14-survey-brief-drug-companies-reduce-patients-access-care-limiting-340b-community-pharmacies

II. THERE IS NO SOUND REASON TO ADOPT A REBATE MODEL, AND THE AGENCY DOES NOT PROVIDE ONE.

Since November 1992, when the 340B program became law, HHS has recognized a single mechanism to make the 340B price available to participating hospitals and other covered entities — an upfront discounted price.[9] In fact, HRSA issued guidance soon after the program's inception, stating that upfront discounts — not rebates — must be made available to 340B covered entities.[10] After decades of successfully relying on this upfront discount system, the agency has now reversed course and decided to embrace a rebate model for all covered entities. The question is for what purpose and why now?

These are critical questions as a matter of law. "Agencies are free to change their existing policies as long as they provide a reasoned explanation for the change." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016). That explanation must "show that there are good reasons for the new policy." *Id*. (quotation marks omitted). And in "explaining its changed position, an agency must also be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account." *Id*. (quotation marks omitted).

HRSA has not satisfied those requirements here. Nor could it. The closest HRSA comes to explaining why it is pursuing a pilot program is its statement in the Notice that the drug companies have made "inquiries … related to different proposed rebate models for the 340B Program." But an agency cannot make such a drastic change simply because a regulated party has asked for it. Not only does that reflect the worst kind of "regulatory capture,"[11] but HRSA must explain why "there are good reasons for it, and that the agency *believes* it to be better, which the conscious change of course adequately indicates." *FCC v. Fox Television Stations, Inc*., 556 U.S. 502, 515 (2009).

The Notice provides none of this required information. That leaves the AHA to look to the two reasons the drug companies have offered for why a rebate model is needed. Both fail to justify the kind of wholesale policy change to a rebate model.

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[9]HRSA has made only one exception to this practice, allowing the use of a rebate model in a limited circumstance for AIDS Drug Assistance Programs that operate differently from other 340B covered entities that directly buy and bill drugs. *See* Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 — Rebate Option, 63 Fed. Reg. 35239 (June 29, 1998).

[10] Limitation on Prices of Drugs Purchased by Covered Entities, 58 Fed. Reg. 27289, 27291 (May 7, 1993); Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25110, 25113 (May 13, 1994).

[11] *See* Lex Fridman Podcast #388, Transcript for Robert F. Kennedy Jr: CIA, Power, Corruption, War, Freedom, and Meaning (July 6, 2023), *at* https://lexfridman.com/robert-f-kennedy-jr-transcript/.

First, drug companies claim rebate models are necessary to reduce the incidence of statutory violations against diversion and duplicate discounts.[12] But the pilot program expressly disclaims any effort to promote this goal. The Notice specifically forbids drug companies from denying rebates on the basis of their subjective allegations of non-compliance. It instead directs concerns about diversion and deduplication to where the 340B statute intends for them to be addressed: "audits and administrative dispute resolution." Thus, even if the agency had a lawful basis for using a rebate model to address program integrity problems — and it does not[13] — this inconsistency between the details of the pilot program and the asserted goal does not pass legal muster. After all, "an [u]nexplained inconsistency' in agency policy is a reason for holding" it to be "an arbitrary and capricious change from agency practice." *Encino Motorcars, LLC*, 579 U.S. at 222.

More fundamentally, 340B hospitals do not have a program integrity problem that needs to be addressed by a rebate model. Drug companies have repeatedly asserted without basis that there is rampant abuse by hospitals of the 340B program.[14] They also assert that HRSA has been deficient in its required oversight of 340B hospitals and other covered entities, auditing "only a tiny fraction" of 340B hospitals participating in the program.[15] Not only are these claims factually incorrect, but the data prove that drug companies — not hospitals — are responsible for the bulk of 340B program integrity violations.

Don't take our word for it. HRSA's own 340B audit data show that between fiscal years (FY) 2018 and 2022, audit findings across 340B hospitals for duplicate discount and diversion decreased by a combined 62%.[16] Only 10.7% of 340B hospital audits had at least one finding of diversion; just 13.2% had a duplicate discount finding in FY 2022.[17] As with any program as regulatorily and operationally complex as 340B, hospitals have adapted their 340B programs to better maintain compliance with all rules and regulations. For example, 340B hospitals have developed robust internal audit protocols to conduct periodic self-audits of their 340B program and, in some cases, leveraged

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[12] The Complaints that the companies and their supporters filed in district court repeatedly insist that rebate models are needed to promote program integrity. *E.g.*, Novartis Compl. 2, 34, 51, 52, 66; Bristol Meyers Squibb Compl. 5, 23, 45, 53; Eli Lilly Compl. 1, 8, 10, 65; Kalderos Amended Compl. 3, 4, 41, 49, 61; J&J Compl. 1, 8, 11, 45, 48, 83, 84,

[13] The AHA's *amicus* briefs have explained by the 340B statute does not permit a rebate model for the purposes of addressing program integrity. *See, e.g.,* Br. of the American Hospital Association, et al., *Novartis Pharmaceuticals Corporation, et al., v. Kennedy*, Nos. 25-5177, 25-5179, 25-5220, 25-5221, 25-5236 (D.C. Cir. Aug. 5, 2025), *at* https://www.aha.org/amicus-brief/2025-08-05-aha-others-defend-hhs-decision-reject-340b-rebate-models-drug-companies.

[14] https://www.advi.com/insight/analysis-of-fy-2021-hrsa-340b-covered-entity-audits/#HRSA-footer-ten

[15] https://phrma.org/resources/phrma-letter-to-hrsa-and-hhs-regarding-duplicate-discounting-in-340b

[16] https://www.aha.org/guidesreports/2025-06-16-more-drug-company-oversight-needed-maintain-compliance-340b-program-rules

[17] *Id.*

technology — at a significant cost — to mitigate against any instances of diversion or duplicate discounts. HRSA's data definitively proves this.

In vivid contrast, between FYs 2018 and 2022, 60% of drug companies had at least one adverse audit finding. And the trends are even more notable with respect to audit findings requiring repayment. In FY 2022, 75% of drug companies that were audited required repayment to 340B hospitals while only 28% of 340B hospitals' audit findings involved any repayments.[18] **The evidence is clear: drug companies, not 340B hospitals, are the entities with a 340B program integrity problem.**

This data further undermines the notion that HRSA is not conducting enough oversight of 340B hospitals. The data show that HRSA conducts approximately 160 audits of 340B hospitals annually — or about 6% of the 340B hospital field. By contrast, it conducts only five audits of drug companies — or about 0.6% of participating drug companies.[19] Put another way, HRSA audits 340B hospitals at ***10 times*** the rate it audits participating drug companies. In combination with the data showing the astonishing rate of audit findings for drug companies in a much smaller sample size, this discrepancy underscores the need for more scrutiny on drug companies — not 340B hospitals. **Thus, drug companies are advocating for a 340B rebate model as a solution to a problem that does not exist. For this reason alone, HRSA should abandon its 340B rebate model pilot program.**

Second, drug companies have asserted that a rebate model is the only way they can comply with requirements under both the IRA and the 340B statute. This is not the case.

The drug companies repeatedly insist that the IRA necessitates a 340B rebate model. For example, Johnson & Johnson claimed in litigation that "the Rebate Model is the *only* mechanism J&J is currently aware of that would enable J&J to meet its statutory obligations under the Inflation Reduction Act […]."[20] This statutory requirement cited by J&J is the lone reference to 340B in the 273-page IRA. This provision, also known as the 340B nonduplication provision, requires drug companies to ensure that they provide dispensing entities access to the lower of either a Medicare negotiated drug's maximum fair price (MFP) or 340B discounted price. Surely, Congress did not contemplate this single reference to 340B as an invitation for the government or drug companies to disregard the 340B statute or upend more than 30 years of precedent of an upfront 340B discount. To the contrary, on two separate occasions, Congress has sent a bipartisan letter to HRSA explicitly objecting to the concept of a 340B rebate model and

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[18] *Id.*
[19] *Id.*
[20] *See* pg. 5, *Johnson & Johnson Health Care Sys. Inc. v. Becerra* (Civil Action No. 1:24-cv-3188 (emphasis added).

asking the agency not to approve it.[21] Therefore, it is more than reasonable to assume that Congress did not want the IRA to be a scapegoat to pursue a 340B rebate model.

Moreover, a rebate model is not the "only" mechanism available to ensure compliance with the nonduplication provision in the IRA. As the AHA communicated to CMS in July 2024[22] and May 2025[23], there is another viable alternative: to require drug companies to make access to the maximum fair price for Medicare negotiated drugs available *prospectively* as is currently done for drugs purchased under the 340B program. Specifically, this alternative would allow dispensing entities, like hospitals and pharmacies, to purchase Medicare negotiated drugs at either the drug's maximum fair price or 340B price, whichever price is lower for that particular drug. Dispensing entities would then submit certain data to CMS' Medicare Transaction Facilitator (MTF), which would verify that the dispensing entity purchased the drug at the correct price. If the purchase was made at the incorrect price, the MTF could facilitate a transfer of funds between the drug company and the dispensing entity to rectify the error.

Under this mechanism, there would be no need for a 340B rebate model. In fact, CMS has acknowledged through final guidance that drug companies need not make the MFP available as a retrospective price and can provide it as a prospective, upfront price if they choose to do so.[24] So, it appears that neither Congress, CMS, nor the underlying statute consider a rebate model "necessary" for drug companies to comply with the law. Instead, drug companies are opting to make the MFP available only retrospectively so that they can claim that a 340B rebate model is necessary to meet their statutory obligations under the IRA. This, too, is a manufactured problem to support an otherwise unnecessary and detrimental policy solution.

Thus, the two primary reasons drug companies have cited in their push for a 340B rebate model are both baseless and insufficient to warrant a fundamental change to the 340B program. This may be why the agency has not cited them in its Notice. But the agency still has allowed the camel's nose to get under the tent by authorizing a pilot program that serves no public policy purpose. All it does is impose an additional layer of costs on the health care system, preventing valuable resources from going to where they belong: patient care.

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[21] https://spanberger.house.gov/uploads/2024/09/Quill-Letter-L20840-Letter-to-HHS-on-JJ-340B-Rebate-Model-Version-1-09-27-2024-@-03-08-PM.pdf & https://spanberger.house.gov/uploadedfiles/201113_final_340b_hhs_letter.pdf

[22] https://www.aha.org/system/files/media/file/2024/07/aha-submits-comments-on-cms-guidance-for-medicare-drug-price-negotiation-program-letter-7-2-24.pdf

[23] https://www.aha.org/lettercomment/2025-05-01-aha-comments-medicare-transaction-facilitator-under-medicare-drug-price-negotiation-program?mkt_tok=NzEwLVpMTC02NTEAAAGaMG_uXVu4rNY55TmiN5eiEZYdx72V58R3Zh_4LbxqCaZeCOIrloE6j-EGoSwthThWmSoKtktux5XSih85vVB1-Z95ruj4SiR8YoMgTZ6szEj42Q

[24] https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

What's more, the flimsiness of the drug companies' explanations for why a rebate model is needed exposes that this effort was never truly intended to improve program integrity or comply with the IRA. It appears that the drug companies have concocted these reasons to mask the true reason why they are so ardently advocating for a 340B rebate model: to chip away at the 340B program and reduce the discounts that they provide to 340B covered entities.

This should not come as a surprise. As HRSA knows well, drug companies have a long track record of undermining the 340B program and its benefits to patients and communities, with a recent example being their unlawful restrictions on accessing 340B discounted pricing through contract pharmacies. In fact, drug companies have all but admitted that they want to use rebate models as a mechanism to usurp HRSA's oversight authority and police the program on their own terms.[25] By even entertaining a limited rebate model, HRSA is rewarding drug companies for their bad behavior and their continued perpetuation of lies about the 340B program and HRSA's performance.

If HRSA rewards drug companies for their repeated abuses, those companies will be incentivized to continue their crusade to undermine the program. The agency has already signaled that it could expand the rebate model pilot program to apply to more drugs, which would give drug companies exactly what they want: a significantly diminished 340B program that puts drug company profits over patient care. HRSA should reject these efforts to undermine the 340B program and restore upfront access to 340B pricing for all drugs. At a minimum, HRSA should not expand this ill-advised pilot program in any way.

III. REBATE MODEL WILL HARM PATIENTS AND PROVIDERS NATIONWIDE

As the agency acknowledges, the rebate model will require hospitals to purchase the 10 Medicare Part D drugs included in the pilot at the drug's wholesale acquisition cost (WAC), the highest sale price for a drug and rarely paid in the market. Our members have informed the AHA that the WAC price for some of these drugs are more than 100 times the 340B price for the drug. For example, the WAC price for a standard fill of Stelara is nearly $14,000 and over $7,000 for Enbrel.[26] With mere weeks to prepare for this pilot program, hospitals have not been able to budget for such an extraordinary increase in their upfront costs.

But even with time to budget, most hospitals lack the necessary cash reserves to float such significant sums of money while waiting for drug companies to pay them back — even for 10 days. Moreover, any cash reserves 340B hospitals may have are allocated to address emergencies such as a natural disaster, mass casualty event or cyberattack.

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[25] *See supra* at note 12.
[26] https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf

In addition, 340B hospitals reported to the AHA that a rebate model would:

1. **Limit their ability to support current levels of community benefits and fund critical patient care programs and services.** 340B hospitals use their savings in many ways, including funding a range of community benefits. In 2020 alone, 340B hospitals provided $84.4 billion in community benefits such as medication therapy management, diabetes education and counseling, and access to free or discounted medications.[27] With the need to float millions of dollars to drug companies, coupled with the potential for rebate delays and denials, 340B hospitals will have fewer funds to devote to providing community benefits. Similarly, 340B hospitals will have fewer savings to devote to maintaining, improving, and expanding access to an array of vital patient programs and services. **This is why it is so critical for HRSA to develop strict safeguards for the pilot program and to abandon any effort to expand the program beyond this limited 10-drug test-case**.

2. **Put hospitals at risk of violating their bond covenants.** 340B hospitals rely on bond financing to raise money for new projects that enhance patient care. Those bonds typically include covenants requiring hospitals to maintain a certain number of days of cash on hand. Paying full price for drugs (even for 10 days) will put hospitals at risk of violating those covenants, which would have calamitous effects on 340B hospitals, including downgrades in credit ratings, increased borrowing costs, lack of access to state-of-the-art medical equipment, and even closure.

3. **Create enormous administrative burdens.** As noted, hospitals would bear the responsibility of providing claims-level data elements to drug companies or risk not getting paid. Having operated under an upfront discount model for three decades, hospitals and health systems have "engendered serious reliance interests" in continuing with that policy. *Fox Television Stations, Inc*., 556 U.S. at 515. Consistent with those interests, our member hospitals tell us that they may need, on average, two additional full-time equivalents (FTEs) to gather the appropriate data, submit the data in the format required under the drug company's IT platform, and track the data to ensure the appropriate rebates are paid. Further, hospitals have conveyed that at least some of the data being required, such as claims for physician-administered drugs, may be impossible to provide in their required timeframes. The pilot program also enables each drug company to establish its own process and IT platforms. With the current list of 10 drugs included in the pilot encompassing nine different drug companies, hospitals could be required to comply with nine different models and programs. Hospitals report that this will only increase the need to hire new staff and/or divert existing staff from patient care to operationalizing this pilot program.

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[27] https://www.aha.org/guidesreports/2023-10-19-340b-hospital-community-benefit-analysis

> Again, this is why HRSA must stand behind its intention to ensure that "no additional administrative costs […] are passed onto covered entities," and make certain that the drug companies pay for what they've asked for. **If the agency really is pursuing a pilot program because the drug companies have asked for it, then those companies must foot the entire bill.**

Before piloting the rebate model, HRSA must balance these adverse impacts on providers and their patients against the unavoidable costs of fundamentally changing the 340B program to appease drug companies. When doing so, the scales will surely tip firmly in favor of maintaining an upfront discount model. At the very least, it counsels strongly in favor of imposing additional clear, robust safeguards against drug company non-compliance, backed by swift, strong penalties for such non-compliance.

We appreciate your careful consideration of these issues. Please contact me if you have any questions or feel free to have a member of your team contact Bharath Krishnamurthy, AHA's director of health policy and analytics, at bkrishnamurthy@aha.org.

Sincerely,

/s/

Chad Golder
General Counsel & Secretary