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May 9, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Kennedy:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including our more than 2,100 340B hospitals, and our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) writes to urge you to reject the effort by several large drug companies to undermine the 340B Drug Pricing Program by imposing a "rebate model," rather than the longstanding "upfront discount" model that the Department of Health and Human Services (HHS) has allowed since the outset of the program. On May 2, 2025, HHS filed a Notice in the United States District Court for the District of Columbia in connection with litigation about these proposed "rebate models." **Because this Notice stated that the Department "expects to be in a position to provide guidance for stakeholders in thirty days," we write now, with great urgency, to explain the ruinous consequences that these "rebate models" will inflict on hospitals, patients and communities across the country.**

The 340B Program is a vital lifeline for hospitals, particularly those serving rural and low-income communities. If HHS authorizes these proposed "rebate models," it would come at the expense of America's most vulnerable patients and communities. We respectfully ask that you deny the drug companies' requests to approve their unlawful "rebate models."

HHS' Notice to the district court correctly explained that "[l]arge-scale implementation of rebate models to effectuate the 340B ceiling price would be a significant change for the 340B Program and its stakeholders." These proposed "rebate models" would fundamentally transform the 340B Program. They would eviscerate HHS' authority to oversee the program in a neutral manner, and hand over enforcement authority to the drug companies. But as true as it is, the statement in HHS' Notice understates the impact of the "rebate model" on hospitals and their most vulnerable patients. *Any* use of "rebate models," whether large-scale or small-scale, would not just be a "significant

change." It would be a *significantly harmful* change. As a bipartisan group of nearly 200 members of Congress wrote, the proposed rebate models "would create significant financial challenges for safety-net hospitals" and would "reduce resources available for providing comprehensive services to patients and communities, undermining the core purpose of 340B." Congressional Letter 1, 2 (Sept. 27, 2024), *at* https://d12t4t5x3vyizu.cloudfront.net/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.

These rebate policies will dramatically erode the 340B discount that Congress intended for them to receive. For starters, hospitals will be forced to advance millions of dollars to the drug companies. "This approach is to the manufacturer's financial benefit because the company retains those sums for a longer time and creates hurdles for covered entities to claim the discount." *Id*. Already "operating under much lower operating margins than non-340B hospitals," *id*. at 2. America's 340B hospitals cannot afford to make zero-interest loans without any guarantee of when — or whether — they will be paid the discounts they are owed by law. They certainly cannot do so based on mere promises by the drug companies to provide rebates in a timely manner. In fact, *hundreds of hospitals* reported to the AHA that these rebate policies could cause them to violate their bond covenants, which would lead to catastrophic financial distress and, for some, permanent closure.

340B hospitals also will have to spend enormous amounts to comply with the rebate policies that could otherwise be used for patient care. This is true under the proposed "large-scale" models or any smaller ones that the drug companies may propose down the road. "Rebate model" policies have no precedent in the three decades since the start of the 340B Program. Hospitals therefore have no existing infrastructure to comply with them — let alone the many different variations and requirements across the hundreds of drug companies that could adopt them. If the drug companies impose any form of a pre-discount "rebate model," many 340B hospitals will be forced to hire new full-time employees to meet the drug companies' demands, and they will have to purchase new technologies to provide the required purchase data and to track the rebates they are owed. In a world of finite resources, 340B hospitals will have no choice but to divert funds away from patient services and toward burdensome compliance with these "rebate models."

The drug companies cannot justify those calamitous consequences. They claim that their "rebate models" are necessary because there is widespread abuse in the 340B program. But the data show otherwise. As we explain below in Section I.C., a careful review of the most recent audit data show that there is comparatively little diversion — and even that number is trending downward. By contrast, audits demonstrate that drug companies are more often violating 340B Program requirements. We urge HHS to reject the drug industry's false narrative that "rebate models" are necessary to maintain for program integrity. At a minimum, in weighing the costs and benefits of approving a "rebate model," we encourage the agency to not let these false claims outweigh the

predictable and considerable adverse effects that they will have on hospitals, patients, and communities.

For these reasons alone, we recommend HHS reject the proposed "rebate models." In addition, we also believe these rebate models are unlawful and should not be approved. As explained below, the 340B statute itself, Supreme Court precedent, longstanding HHS regulations, *and even the words of the drug companies themselves* make clear that these proposed rebate models are incompatible with the law. The drug companies may be dissatisfied with the 340B statute or how it has been enforced, but that does not permit them to try to enforce the statute themselves through their illegal "rebate models." If the agency was to approve this unlawful self-enforcement, it would allow the drug companies to "capture" the agency that is supposed to regulate it.

The AHA appreciates HHS' careful evaluation of its options. We hope that the promised guidance will account for the legal and practical considerations explained below. And we hope that you reject the drug companies' effort to further profit at the expense of the "340B hospitals [that] perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022) (Kavanaugh, J.).

Our detailed comments follow.

I. The Drug Company "Rebate Model" Proposals Are Unlawful

The drug companies that proposed "rebate models" have made no secret about why they wish to make this sea change in the 340B program. They all assert that there is abuse in the 340B Program, and that HHS has not taken sufficient action to address this alleged abuse. In their view, these "rebate models" are the only way to prevent this alleged abuse. Large-scale implementation of these models, they insist, will allow the drug companies to enforce the statute themselves. As explained below in Section I.C, *the government's own data* does not support their allegations. But even if their allegations were true, the 340B statute and decades-old HHS regulations bar unilateral self-enforcement by these drug companies. Thus, any approval of these rebate models itself would be unlawful and subject to immediate challenge under the Administrative Procedure Act.

A. The 340B Statute Does Not Grant Drug Companies The Authority To Enforce Program Requirements At All, Much Less Through A "Rebate Model"

The text and structure of the 340B statute make clear that Congress did not intend for participants in the 340B Program to engage in self-enforcement. Quite the contrary, the 340B statute contemplates that HHS will always have a role in enforcing program requirements. Consider the following provisions:

- 42 U.S.C. § 256b(a)(5)(C) provides for audits to enforce the statute's prohibitions on diversion and duplicate discounts. This provision gives audit responsibility to the "Secretary and the manufacturer of a covered outpatient drug" — not the manufacturer alone. *Id*. It also gives the Secretary — and not the manufacturer —the authority to develop procedures "relating to the number, duration, and scope of audits." *Id*.

- 42 U.S.C. § 256b(a)(5)(D) relatedly provides for "[a]dditional sanction for noncompliance" with the diversion and duplicate discount provisions, but only *after* an audit is completed and only *after* the covered entity is given an opportunity for "notice and hearing." *Id.* This subsection also specifies that the sanction will be "an amount equal to the reduction in the price of the drug," *i.e*., exactly what the drug companies will refuse to pay up-front (without any audit, notice, or hearing) under the rebate policy. *Id.*

- 42 U.S.C. § 256b(d)(2) directs the Secretary to "provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount." *Id.* It also specifies certain compliance improvements, including the "imposition of sanctions, in appropriate cases *as determined by the Secretary*." *Id*. (emphasis added).

- 42 U.S.C. § 256b(d)(3) formalizes a statutory administrative dispute resolution (ADR) process with HHS playing a central role. Not only does the statute require the Secretary to "promulgate regulations to establish and implement" the ADR process, but it requires that these regulations "designate or establish a decision-making official or decision-making body *within the Department of Health and Human Services* to be responsible for reviewing and finally resolving claims." *Id*. (emphasis added).

These structural features prove that Congress did not want drug companies to engage in unilateral enforcement of the 340B statute. Instead, it sought to preserve HHS' vital role as a neutral referee in disputes between drug companies and covered entities.

The Supreme Court has recognized this. As the Court held in *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 119-20 (2011), Congress "centralized [340B] enforcement in the "government," creating a "unitary administrative and enforcement scheme." Congress did *not* give an "auxiliary enforcement role" to participants in the 340B program. *Id*. at 117. The drug companies made this exact point in the recent litigation over the "rebate models," arguing that "*Astra* forbids[ ] the *private* enforcement of 340B program requirements *in all forms*." Pls.' Joint Opp'n to Mot. to Intervene (Dkt. 22) at 10, *Novartis Pharm. Corp. v. Becerra*, No. 25-cv-117 (D.D.C. Jan. 31, 2025) (second emphasis added and quotation marks omitted); *see id*. at 9 (quoting twice *Astra* for same proposition). Yet that is exactly what the drug companies seek to do with their "rebate models." They seek to privately enforce the 340B statute's requirements outside of the processes and procedures that Congress created to address those violations.

Astra also is important for a second reason. It made no difference to the *Astra* Court that there had been various "reports of inadequate HRSA enforcement." 563 U.S. at 121. The drug companies point to similar reports in their effort to paint a (false) picture of rampant program abuse and deficient HHS performance. But in *Astra*, the Court explained that Congress was aware of those kinds of reports when it amended the 340B statute in 2010, and yet it still did not unleash program participants to go out and fend for themselves. Rather, Congress chose to reinforce the ADR process and to "strengthen and formalize HRSA's enforcement authority." *Id*. at 121-122. Thus, *Astra* holds that private participants in the 340B Program — be they covered entities in that case or drug companies with their "rebate models" — cannot seek to unilaterally enforce the statute themselves.

Finally, the 340B statute sets forth a carefully calibrated enforcement regime. All of the enforcement processes included in the statute are to be conducted *after* covered entities have paid *discounted* 340B prices. Specifically, the 340B statute contemplates: 1) some awareness of a past violation, which then kicks off; 2) a review of completed transaction records, followed by; 3) a determination and remedy by HHS, either under the ADR process, *see* 42 U.S.C. § 256b(d)(3)(B)(i), or through agency-imposed sanctions and civil monetary penalties, *see id*. §§ 256b(a)(5)(D), 256b(d)(2)(B)(v); *see generally Am. Hosp. Ass'n v. HHS*, No. 4:20-cv-08806, 2021 WL 616323, at *6 (N.D. Cal. Feb. 17, 2021) ("Congress made explicit that alleged 340B Program violations are to be first adjudicated by HHS through an established ADR process. This process provides the agency an initial opportunity to develop rules and regulations applicable to the enforcement of the 340B Program requirements."). Neither the statutory audit process nor the statutory ADR process contemplates a regime where drug companies can conduct their own free-wheeling self-enforcement *before* providing 340B discounts, with the authority to refuse such pricing based on a drug company's unilateral belief that violations of the statute are occurring.

B. Longstanding HHS Guidance Bar Drug Companies From Unilaterally Enforcing Program Requirements Through A "Rebate Model"

HHS has long and consistently interpreted the 340B statute to preclude what the drug companies seek to do here. In 1993, the Health Resources and Services Administration (HRSA) sought public comment to inform its superintendence of the 340B Program, particularly with regard to the statutory bars on diversion and duplicate discounts. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 58 Fed. Reg. 68,922 (Dec. 29, 1993). Five months later, the agency issued a Final Notice stating: "A manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions." Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59

Fed. Reg. 25,110, 25,113 (May 13, 1994).[1] **HRSA also specifically stated that drug companies may *not* require hospitals to submit information about "drug acquisition" and "purchase" as a condition for 340B discounts. *Id*. at 25,113-114.**[2]

Additional HHS guidance reinforces this understanding of the 340B statute. In 1996, the Department began requiring manufacturers to demonstrate "reasonable cause" before conducting an audit. Manufacturer Audit Guidelines and Dispute Resolution Processes, 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996); *see id*. at 65,406 (explaining that the "reasonable cause" standard "will ensure that the audits are performed where there are valid business concerns *and are conducted with the least possible disruption to the covered entity*" (emphasis added)). The Secretary did not want a free-for-all where dozens of different drug companies had "the right to routinely conduct an audit as a normal business practice without the need for Departmental approval." *Id*.

The proposed "rebate models," by contrast, are not based on individualized suspicion or even "reasonable cause" that a particular violation has occurred. They cast an exceedingly wide net, demanding purchase data as a matter of course, all based on the generalized belief that some abuse surely must be occurring. The 340B statute and agency guidance bar this kind of fishing expedition — especially because they will certainly not cause "the least possible disruption to the covered entity." *Id*. The drug companies cannot, as part of their normal business practices, require covered entities to provide swaths of information in advance, *before* they pay covered entities at the 340B price.

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[1] The only time in 30 years that HRSA exercised its statutory authority to approve a rebate model, in the narrow and distinguishable context of State AIDS Drug Assistance Programs, it reemphasized this longstanding limitation on drug company behavior. *See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 — Rebate Option*, 63 Fed. Reg. 35,239, 35,240 (June 29, 1998) ("In addition, manufacturers and covered entities are referred to 59 FR 25113 for a reminder that 'a manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions.'"). **HHS' briefing and oral argument in the recent litigation persuasively explained the differences between the large-scale "rebate model" proposals and this lone historic approval. Any rejection of these models in HHS' forthcoming guidance should expressly distinguish this prior approval on similar grounds**.

[2] Although that guidance did allow manufacturers to request "standard information," Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. at 25,113-114, there is nothing "standard" about the current demands under the "rebate models." Most important, the term "standard information" must be understood in light of the rest of HRSA's guidance. By explicitly barring demands for "drug acquisition" and "purchase" information, the term "standard information" cannot include exactly the kind of data that the drug companies now demand under their rebate policy. Nor can it include the scope and quantity of data at issue here. The burden and administrative costs associated with the large-scale implementation of these "rebate models" are substantial, which is further evidence that they are not at all "standard." And if all of that were not enough — and it surely is — another portion of the Final Notice seems to equate "standard information" with "routine information necessary to set up and maintain an account." Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. at 25,112. The "rebate models" require far more information than that.

In fact, the same HHS audit guidelines that set forth the "reasonable cause" standard also responded to public comments insisting that "[m]anufacturers should not be required to continue to sell to a covered entity at the mandated price once an audit has been initiated, particularly since reasonable cause has already been demonstrated." 61 Fed. Reg. at 65,408. HHS rejected that proposal:

> Manufacturers must continue to sell at the statutory price during the audit process. Once the audit has been completed and the manufacturer believes that there is sufficient evidence to indicate prohibited entity activity, then the manufacturer may bring the claim to the Department through the informal dispute process. *Not until the entity is found guilty of prohibited activity and a decision is made to remove the entity from the covered entity list, will the manufacturers no longer be required to extend the discount*. *Id*. (emphasis added).[3]

Thus, the Secretary did not want drug companies to unilaterally deny 340B up-front discounts based on a manufacturer's mere suspicion of prohibited activity — precisely what the drug companies seek to do with their "rebate models." Here, the drug companies would not only deny 340B discounts before a completed statutory audit; they would deny those discounts *at the time of sale* (and even absent any suspicion of prohibited activity).

HHS has used its regulatory authority to channel disputes through an orderly audit and ADR process, during which covered entities would continue to be paid the discounted 340B pricing. This again proves that any effort by drug companies to police the 340B statute in its sole discretion — before providing 340B discounts and only in exchange for purchase data — is incompatible with HHS' longstanding view of the law.

C. The Drug Companies' Allegations of Program Abuse Are Incorrect

The drug companies insist that a "rebate model" is necessary because there is rampant abuse in the 340B Program and the statutory audit process is flawed. It is no surprise that the drug industry would say this; they have a strong financial interest in maligning the 340B Program and suggesting that hospitals are abusing it. But even leaving that rank self-interest to one side, the drug companies are simply wrong. **The facts show that not only are 340B hospitals already subject to disproportionately greater program oversight, but that they vastly outperform drug companies in terms of program compliance**.

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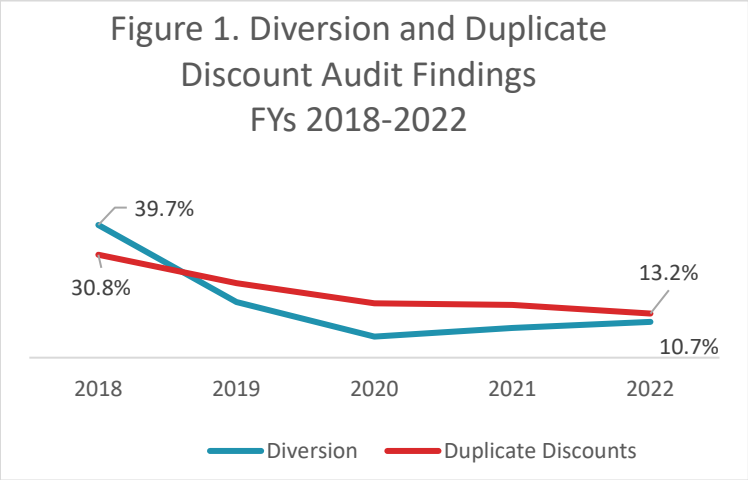
[3] Congress was presumably aware of this guidance when it amended the 340B statute in 2010 to codify an audit as a prerequisite for the ADR process. *See Lorillard v. Pons*, 434 U.S. 575, 581 (1978) ("[W]here, as here, Congress adopts a new law incorporating sections of a prior law, Congress normally can be presumed to have had knowledge of the interpretation given to the incorporated law, at least insofar as it affects the new statute."); *cf*. *Astra*, 563 U.S. at 121-122.

HHS' audit program dates back more than a decade. The agency began auditing 340B covered entities in 2012 and performs 200 audits annually, of which approximately 160 are of 340B hospitals (or about 6% of participating hospitals). HHS began audits for drug companies in 2015 and performs approximately five audits every year (or about 0.6% of participating drug companies). The results of these audits are posted publicly on HRSA's 340B Program integrity website,[4] including the nature of any audit findings and the corrective action taken, including whether repayment was required.

The AHA has reviewed the publicly available federal audit data for both 340B hospitals and drug companies over a 5-year period from fiscal years (FY) 2018-2022.[5] Duplicate discount and diversion findings in 340B hospital audits have plummeted, reflecting very high rates of compliance in recent years. Over a five-year period, hospitals with either finding dropped by 62.1%, from 56.4% in FY 2018 to 21.4% in FY 2022. When broken down by type of finding, in FY 2018, 30.8% of 340B hospital audits included at least one duplicate discount finding. This percentage dropped to 13.2% by FY 2022 or a 57% decrease over this 5-year period. Similarly, in FY 2018, 39.7% of audited 340B hospitals had at least one diversion finding. That dropped to just 10.7% in FY 2022 or a 73% decrease over this 5-year period. The chart below captures this data.



In contrast to 340B hospitals, drug company audits reveal a consistent pattern of *non-compliance*. 30 audits were conducted for drug companies between FY 2018 and FY 2022, with 60% of these audits having at least one adverse finding. Of those drug companies that had at least one adverse finding, 93% were required to issue repayments to covered entities, underscoring a shocking pattern of non-compliance among drug companies.

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[4] https://www.hrsa.gov/opa/program-integrity
[5] FY 2022 is the latest year of complete data available. Currently, HRSA has only posted 164 of its 200 audit results for FY 2023.

The facts here are simple: 340B hospitals are meeting program rules and regulations. The drug companies are not. Hospitals have made significant improvements in compliance over the past five years, which likely reflects the work they have done with third-party administrators and other entities to conduct regular and comprehensive internal self-audits of their 340B programs.[6] Meanwhile, drug companies continue to demonstrate a high degree of non-compliance with program rules and regulations. And all of this comes with a stunningly disproportionate audit rate, with HHS scrutinizing 340B hospitals *at 10 times the rate of drug companies* (6% vs. 0.6%).

Given these facts, the drug companies' assertions that a "rebate model" is needed to ensure program integrity should not be taken seriously. Not only are hospitals complying with their statutory requirements, but the statutory audit process is working. Accordingly, even if HHS had the legal authority to permit the drug companies to use "rebate models" to police diversion — and it does not — it would be arbitrary and capricious to do so because the "rebate model" is aimed at solving a problem that doesn't exist *and* creates a devastating set of problems on its own for hospitals, patients and communities (*see infra* at Section II).[7]

D. *Novartis Pharms. Corp. v. Johnson* Does Not Authorize The Drug Company "Rebate Models"

The D.C. Circuit's decision in *Novartis Pharms. Corp. v. Johnson*, does not undermine HHS' interpretation of the 340B statute. Nor does it authorize the proposed "rebate models." *See Novartis*, 102 F.4th at 464 ("We do not foreclose the possibility that other, more onerous conditions might violate the statute."); *Novartis Pharms. Corp.,* 2021 WL 5161783, at *9 ("The statute's plain language, purpose, and structure do not … *permit* all conditions." (emphasis in original)). That decision upheld a United Therapeutics policy requiring "covered entities to provide claims data associated with all 340B

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[6] https://www.340bpvp.com/Documents/Public/340B%20Tools/independent-audit-request-for-proposal-checklist.docx

[7] The drug companies also have claimed that a "rebate model" is necessary to comply with the Inflation Reduction Act (IRA) Drug Negotiation Program. The AHA has sent two letters to HHS explaining why this is incorrect. *See* Letter from Ashley Thompson, Senior Vice President, Public Policy Analysis and Development, American Hospital Association, to Kim Brandt, Chief Operation Officer and Deputy Administrator of the Center for Medicare Centers for Medicare & Medicaid Services (May 1, 2025), https://www.aha.org/lettercomment/2025-05-01-aha-comments-medicare-transaction-facilitator-under-medicare-drug-price-negotiation-program; Letter from Ashley Thompson, Senior Vice President, Public Policy Analysis and Development, American Hospital Association, to Meena Seshamani, M.D., Ph.D, Deputy Administrator and Director of the Center for Medicare, Centers for Medicare & Medicaid Services (July 2, 2024), https://www.aha.org/lettercomment/2024-07-02-aha-submits-comments-cms-guidance-medicare-drug-price-negotiation-program We would also draw your attention to (and incorporate here) an *amicus brief* filed by 37 state and regional hospital associations in the litigation over the "rebate models." That brief not only explains why the drug companies' arguments about the IRA are incorrect, but it persuasively refutes their claims about program abuse, the "replenishment model" for inventory management, and the AIDS Drug Assistance Programs.

contract pharmacy orders to a third-party platform, to facilitate efforts to police diversion and duplicate discounts." *Novartis,* 102 F. 4th at 458; *see Novartis*, 2021 WL 5161783, at *4 ("United Therapeutics also requires all covered entities using contract pharmacies to regularly provide claims data to [United Therapeutics] via a third-party platform, among other things, allowing [the manufacturer] to confirm that contract pharmacies are genuinely acting on behalf of a covered entity." (quotation marks omitted)). But United Therapeutics' policy was *meaningfully different* from the proposed "rebate models." It dealt *only* with contract pharmacies and drug company limits related to distribution. *See Novartis*, 102 F.4th at 461-462 ("HRSA invokes the statutory audit and dispute-resolution mechanisms.… [T]hey serve to ensure compliance with the various obligations that section 340B imposes.… HRSA reasons that this enforcement scheme is carefully calibrated, which tends to suggest that it is exclusive. Perhaps so, but that at most shows that section 340B establishes the precise metes and bounds of audits and administrative adjudications. It does not suggest that contractual limits *on distribution* are unlawful." (emphasis added and internal citation omitted)).

The differences between these contexts are determinative. In the contract pharmacy context, *Novartis* found the statute to be silent as to distribution. *Id*. at 460. Here, the statute includes "carefully calibrated" compliance, audit, and dispute resolution procedures that do not permit unilateral drug company enforcement. *Id*. at 462. In the contract pharmacy context, drug companies and HRSA could *not* audit those pharmacies because the 340B statute does not provide for audits of third parties. Here, drug companies *can* audit 340B hospitals, provided they follow the appropriate processes. These distinctions are dispositive, as they directly implicate the textual and structural features discussed above that are incompatible with the rebate model.

More fundamentally, the scope of proposed "rebate models," and the consequences to hospitals for violating them, are even more drastic than anything at issue in *Novartis*. United Therapeutics' policy did not deny 340B discounts to hospitals altogether. It refused to sell *only to contract pharmacies* if data was not provided. *See* Pl.'s Compl. (Dkt. 1) Ex. 3 at 6, *United Therapeutics Corp. v. Espinosa*, No. 21-cv-1686, 2021 WL 5161783 (D.D.C. Nov. 5, 2021). A hospital still could obtain 340B pricing if it distributed a drug from its in-house pharmacy. Here, the "rebate models" would *completely deny* hospitals their 340B discounts if those covered entities refuse to surrender important purchase data or assure program compliance.

It is not too much to say that the proposed "rebate models," unlike United Therapeutics' policy, strikes at the heart of the 340B Program. Rather than merely addressing *where* 340B drugs can be purchased, the "rebate models" touch on the core function of the Program: Whether 340B discounts are provided at all. This runs headlong into HRSA's three-decade-old ban on drug companies conditioning 340B discounts on their own satisfaction about a covered entity's compliance or the handover of purchase data. Because *Novartis* adjudicated a far narrower set of drug company conditions, it has no bearing on the policy at issue here.

E. The "Patient Definition" Component Of Sanofi's "Rebate Model" Is Unlawful

Sanofi-Aventis, a French drug company with approximately $45 billion in revenue in 2024, proposes a unique component in its "rebate model." Unlike the other drug companies, it proposes to demand purchase data from covered entities so that it can unilaterally "validate that the patient to whom the drug was dispensed for the specific 340B pharmacy claim is a patient of the covered entity." If Sanofi, in its unilateral discretion, decides that a patient does not meet the relevant criteria, it will refuse to issue a rebate to a covered entity.

For the above reasons, Sanofi's proposed enforcement of a patient definition is unlawful. This component of Sanofi's model is just a particular instance of a private entity seeking an "auxiliary enforcement role." But as noted above, *Astra* bars that private enforcement role.

Sanofi's counterarguments lack merit. It has contended in litigation that "[n]othing in Section 340B requires that Sanofi must nonetheless provide 340B pricing for drugs that Sanofi knows have *already been* dispensed to individuals who are not patients of the covered entity." Mem. of Points and Authorities in Support of Pl.'s Mot. for Summary Judgment (Dkt. 27-1) at 30. But when Sanofi demands purchase data from hospitals and denies the 340B discount, it does not *already know* that someone is not a patient. Sanofi may *want* purchase information so that it can figure out who is not a patient. But there is a world of difference between actually "knowing," on the one hand, and demanding purchase data "in order to know," on the other.

And as clearly as the 340B statute precludes diversion, it also sets forth a carefully calibrated regime where suspected diversion first must be audited and then addressed in the ADR process. *See* 42 U.S.C. § 256b(a)(5)(C); 42 U.S.C. § 256b(d)(3)(B)(iv). That regime does not permit Sanofi to demand purchase data from 340B hospitals simply because it wants to know, in advance, who may not be a patient under HRSA's 1996 guidance. As Sanofi admitted in its litigation filings, if it later determines that someone is not a patient, it can "claw back the discount from the diverting covered entity on the back end." Mem. of Points and Authorities in Support of Pl.'s Mot. for Summary Judgment (Dkt. 27-1) at 31. But the 340B statute, decades-old agency guidance, and *Astra all* require Sanofi to follow certain procedures to get to that point. They do not allow Sanofi to demand purchase data from 340B hospitals as a precondition for discounts, long before an audit or ADR process is completed, so that the company can unilaterally police diversion and self-enforce a patient definition.

For all of these reasons, the drug companies' proposed "rebate models" are incompatible with the 340B statute and time-honored HHS guidance. Consequently, HHS would not be permitted by law to approve these rebate models even if it wanted to do so.

II. The Drug Company "Rebate Models" Will Have Devastating Consequences for 340B Hospitals

Even if HHS could lawfully approve the proposed "rebate models," it should not for policy reasons. It is universally recognized that the purpose of the 340B Program is to enable certain hospitals and clinics 'to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'" *Am. Hosp. Ass'n v. Hargan*, 289 F.Supp.3d 45, 47 (D.D.C. 2017) (quoting H.R. Rep. No. 102–384, pt. 2, at 12 (1992)); *see Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020), *rev'd sub nom. Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724 (2022) (quoting same language from the House Report). The proposed "rebate models" will do the opposite. They will force hospitals to constrict services, reach fewer vulnerable patients, and in some instances, potentially close their doors.

The AHA surveyed its members in the winter of 2025 to better understand the impact of "rebate models" on its members. The findings from this survey include:

1) **Ninety-nine percent of hospitals indicated that a retrospective rebate model would limit their ability to fund critical patient programs and services**. In addition, many hospitals would be unable to stock certain drugs if they were forced to pay the full amount up-front. As a result, patients would lose access to vital, life-saving medication.

2) **The rebate model would require 340B hospitals to subsidize millions of dollars to drug companies by purchasing certain outpatient drugs at a higher price (e.g., wholesale acquisition cost). Some hospitals have indicated this alone could result in more than $10 million in added costs.** Many 340B hospitals already operate on thin or negative margins. After all, these hospitals serve our most vulnerable populations, including millions of Medicare and Medicaid beneficiaries. They cannot absorb the financial strain of having to float millions of dollars.

3) **One hundred percent of hospitals reported increased operational costs due to the proposed "rebate model.**" The "rebate models" require 340B hospitals to do two things: provide data to drug companies and then track whether it received the discount. At both ends, hospitals will be required to spend considerable resources, all to obtain a discount that they are entitled to under the law. Among other things, hospitals will be required to hire new full-time employees, develop or purchase new software, and incur the costs of filing challenges to inevitable unjustified denials of the 340B discounts. As HHS knows, moreover, multiple drug companies have sought authority to impose "rebate models," and many more will follow if these applications are approved. Critically, not every drug company will impose the same requirements, use the same data fields or feeds, accept the same electronic or manual formatting, rely on the same vendors, have the same contractual

language, or provide rebates on the same timetables. Each variable will add to the administrative costs associated with these "rebate models." So when thinking about these new costs and burdens, HHS — like the AHA's members — must think about them exponentially.

4) **Nearly 200 hospitals reported that floating millions of dollars to drug companies would reduce their cash on hand enough to risk violating their bond covenants**. According to an August 7, 2024, report from the independent ratings agency S&P Global, median days cash-on hand have plummeted to a 10-year low for U.S. hospitals. *See* Laura Dyrda, *Hospital average days cash on hand hit 10-year low: S&P*, Becker's Hospital CFO Report (Aug. 9, 2024), at https://www.beckershospitalreview.com/finance/hospital-average-days-cash-on-hand-hit-10-year-low-s-p.html. Indeed, a second independent report confirms that, from February 2022 to February 2024, the number of days cash-on-hand for hospitals and health systems has declined by 25.4%. *See* Jay Asser, *Hospitals' Cash Reserves Diminished in Recent Years*, Health Leaders (Apr. 4, 2024), *at* https://www.healthleadersmedia.com/finance/hospitals-cash-reserves-diminished-recent-years. According to that report, "[t]he steep decrease … highlights continued financial uncertainties for the sector, as having lower cash reserves means hospitals are less prepared for unexpected emergencies or sudden market changes." *Id*. The unilateral imposition of a policy in which hospitals must advance millions of dollars from their cash reserves to drug companies easily qualifies as a "sudden market change" that many 340B hospitals are not financially prepared for.

To put an even finer point on it, as nearly 200 hospitals reported to the AHA, these "rebate models" put 340B 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 amount of days cash-on-hand. *See* Steven Shill, *Healthcare providers face a growing risk of violating debt covenants*, Healthcare Financial Management Magazine (Feb. 2022), *at* https://www.bdo.com/getmedia/bdd99fa0-6f39-4f70-b28d-accf0ba66ea2/0222_HFM_Debt-Covenants.pdf. For many hospitals, the "rebate models" would cause cash-on-hand would drop low enough to risk violating their bond covenants. This would have calamitous effects, including downgrades in credit ratings, increased borrowing costs, lack of access to state-of-the-art medical equipment, and more. Worst of all, "[v]iolating a debt covenant can have a downward spiral effect on an organization's ability to continue *as a going concern*." *Id*. (emphasis added). That consequence — closing a hospital's doors — is obviously antithetical to the 340B statute's purpose.

Respectfully, we believe the Administration cannot permit drug companies to wreak these consequences. If the proposed “rebate models,” are approved, there is no doubt that patients will suffer, as hospitals will be unable to fund the same level and scope of health care services.

The AHA appreciates your thoughtful consideration of this critical issue, and we would look forward to discussing it further. Please contact me if you have questions or feel free to have a member of your team contact Aimee Kuhlman, AHA vice president of advocacy and grassroots, at akuhlman@aha.org.

Sincerely,

/s/

Chad Golder
AHA General Counsel and Secretary

CC: The Honorable Mehmet Oz, M.D., Administrator, Centers for Medicare & Medicaid Services
CC: The Honorable Thomas J. Engels, Administrator, Health Resources and Services Administration