UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR. Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA,

Defendants.

Case No.

**MOTION FOR TEMPORARY RESTRAINING ORDER WITH INCORPORATED MEMORANDUM OF LAW**

**REQUEST FOR IMMEDIATE RELIEF**

## INTRODUCTION

More than three decades ago, Congress created a drug pricing program that is a financial lifeline for safety-net healthcare providers. This lifeline, known as the "340B Program," is now in serious jeopardy due to a hastily made, ill-considered, and unlawful decision by the U.S. Department of Health and Human Services ("HHS") and its agency, the Health Resources and Services Administration ("HRSA"). Hospitals in Maine and across America serving rural and other underserved communities now face imminent and irreparable injury, both in hundreds of millions of dollars in costs they cannot afford and inevitable disruptions to patient care. With the situation becoming increasingly dire, judicial intervention is necessary.

Defendants recently announced a program—the "340B Rebate Model Pilot Program" ("Rebate Program")—that would force safety-net hospitals to pay "significantly higher prices" to drug companies starting on January 1, 2026. *See* Ex. 1 at -66. Stunningly, Defendants just last year stopped drug companies from enacting similar programs, noting that rebates would "disrupt how the 340B program has operated for over thirty years" and citing a litany of cost- and burden-related issues. *Id.* Defendants now try to impose the same costs and burdens without addressing these concerns or explaining their about-face. Indeed, Defendants received over 1,100 public comments on their program, but as of this filing, have not responded to any. Instead, they are racing to a January 1 start date that will have calamitous effects on safety-net hospitals and their patients.

Defendants' actions violate the most basic and well-established principles of administrative law. The decisions to reverse course on a 33-year policy without explanation and leave 1,100 comments fully unconsidered are paradigmatically "arbitrary and capricious." *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983). Defendants have not offered any well-reasoned explanation. *FCC v. Prometheus Radio Project*, 592 U.S. 414,

423 (2021). They have not accounted for the reliance interests of thousands of safety-net providers in underserved communities. *DHS v. Regents of the Univ. of Cal.*, 591 U.S. 1, 33 (2020). They have not considered massive costs that threaten to close these providers. *Mexican Gulf Fishing Co. v. U.S. Dep't of Com.*, 60 F.4th 956, 973 (5th Cir. 2023). In failing to properly weigh costs and benefits, not only have Defendants ignored an "important aspect of the problem," *Ohio v. EPA*, 603 U.S. 279, 293 (2024) (citation omitted), but their program is "substantively unreasonable," *Multicultural Media, Telecom & Internet Council v. FCC*, 873 F.3d 932, 936 (D.C. Cir. 2017). And they have not considered obvious and less burdensome alternatives, *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 59 (D.C. Cir. 2015), instead improperly resorting to predetermined results, *New York v. U.S. Dep't of Com.*, 351 F. Supp. 3d 502, 663 (S.D.N.Y. 2019), *aff'd in part, rev'd in part on other grounds*, 588 U.S. 752 (2019).

Plaintiffs are safety-net hospitals that rely on the 340B Program and membership organizations representing more than 2,000 340B providers. Compl. ¶¶ 13–18. Defendants' decision to hastily implement this unlawful Rebate Program is causing irreparable harm to the very providers the 340B Program is meant to support. Struggling hospitals will spend millions of dollars to comply with this unlawful program, none of which can be recovered. And hospital money earmarked for patient care instead will now be diverted to drug companies, inhibiting providers' ability to fulfill their missions and deliver healthcare to the neediest Americans. Plaintiffs therefore ask this Court to issue a temporary restraining order. *See* Fed. R. Civ. P. 65.

## BACKGROUND

Congress created the 340B Drug Pricing Program in 1992 to give safety-net healthcare providers (known as "covered entities"[1]) access to prescription drugs at significantly discounted

[1] Covered entities include, for example, federally qualified health centers and hospitals that serve a disproportionate share of Medicare, Medicaid, and low income and uninsured patients. 42 U.S.C. § 256b(a)(4).

prices. Pub. L. No. 102-585 § 602 (1992). Under the 340B Program, HRSA calculates a "ceiling price" to set the maximum price drug companies can charge 340B providers. 42 U.S.C. § 256b(a)(1). This ceiling price is a fraction of what drug companies would otherwise charge. To encourage drug company participation in the 340B Program, Congress conditioned federal health insurance coverage of their products on participation. *Id.* § 1396r-8(a)(1); *id.* § 256b(a).

Since the 340B Program's inception, Defendants have required drug companies to provide statutory discounts at the time of the sale, a requirement known as the "upfront discount." *See* 42 U.S.C. § 256b(a)(1); 58 Fed. Reg. 27289, 27291–92 (May 7, 1993). Many 340B providers operate on thin (or negative) margins and cannot afford market prices for drugs without sacrificing patient care. Golder Decl. ¶ 36. The upfront discount honors the 340B Program's purpose by allowing 340B providers "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12 (1992).

Over the years, drug companies have repeatedly tried to institute a "rebate" model, under which safety-net providers would be forced to pay them full market price, known as the wholesale acquisition cost ("WAC"), and then seek reimbursement for the difference between the WAC and "ceiling price" only after administering the drugs and submitting detailed claims data to the drug companies. Such a change would impose millions, if not billions, of dollars of costs on covered entities. *First*, a rebate system would involve vast administrative costs to submit, track, recover, and potentially resolve disputes over rebates. *Second*, it would force 340B hospitals to essentially provide drug companies with interest-free loans while awaiting refunds due by law. *Third*, a rebate system would allow drug companies to slow and stymie rebates, thereby withholding statutorily owed discounts based on technicalities and other mischief. *See* Golder Decl. ¶¶ 22, 28, 30–38.

HRSA has historically rejected drug companies' rebate proposals and required upfront

discounts. In 2024, for example, HRSA stopped multiple drug companies from deploying rebate programs. In doing so, HRSA articulated numerous costs and drawbacks of a rebate model. *E.g.*, Compl. ¶¶ 43–46, 48; Ex. 1 at -66; Ex. 4 at -292; Ex. 5 at -342. It told companies that a "shift [to a rebate model] would disrupt how the 340B Program has operated for over thirty years. As a result of this shift, covered entities, including those which primarily serve rural and underserved populations, would need to pay significantly higher prices on prescription drugs at the time of purchase." *Id.* HRSA identified multiple concerns about abandoning the upfront discount model, including: (1) how a rebate model would affect "the scope and breadth of health care access for patients served by affected covered entities"; (2) how it would add burdens for covered entities, "particularly those that are the sole or primary source of health care in a rural or underserved community"; (3) the grounds on which a drug company would deny a rebate claim; (4) what process would govern the adjudication of disputes about rebates and appeals of denials; (5) how drug companies planned to protect claims information they collect; and (6) how the companies planned to issue refunds. Ex. 1 at -66–68; Ex. 4 at -292–94; Ex. 5 at -342–44.

Several drug companies sued Defendants.[2] While defending themselves, Defendants again repeatedly noted the risks and costs of introducing rebate models to the 340B Program. For example, in litigation against Johnson & Johnson ("J&J"), Defendants noted in April 2025 that HRSA "has long envisioned upfront discounts as the preferred price reduction mechanism" and that a rebate model "would 'create significantly higher up-front costs for covered entities.'" Dkt. 41-1 at 18–20, *J&J v. Kennedy*, No. 1:24-cv-03188 (D.D.C. Apr. 2, 2025).[3] In an August 1, 2025

[2] *See* Doc. 2128443 at i–iv, *Novartis Pharms. Corp. v. Kennedy*, No. 25-5177 (D.C. Cir. Aug. 1, 2025).

[3] The presiding courts in these cases agreed, explaining that covered entities would "be forced to incur higher carrying costs for these drugs, essentially floating revenue to drug manufacturers" and "reduc[ing] the hospitals' resources available for other patient care." *J&J Health Care Sys. Inc. v. Kennedy*, 2025 WL 1783901, at *12–13 (D.D.C. June 27, 2025) (alteration in original); *see also Eli Lilly & Co v. Kennedy*, 2025 WL 1423630, at *12 (D.D.C. May 15, 2025) ("[T]the impact of a rebate float was a relevant factor the agency was entitled to take into consideration.").

brief filed with the D.C. Circuit, Defendants further flagged concerns, noting that "[u]nlike discounts, rebates require covered entities to spend more money upfront and put greater financial pressure on those safety-net programs." Doc. 2128443 at 2, *Novartis Pharms. Corp.*, No. 25-5177.

But at the same time Defendants were highlighting the risks of a rebate model in court, HRSA abruptly launched a 340B rebate program that would have a devastating impact on 340B providers and their patients. On July 31, 2025, HRSA announced a new "340B Rebate Model Pilot Program," followed by a notice in the *Federal Register* ("Notice"). The Notice stated Defendants would allow certain drug companies to mandate 340B rebate pricing for specific drugs, effective January 1, 2026. 90 Fed. Reg. 36163 (Aug. 1, 2025). Covered entities would be required to purchase drugs at full WAC, and wait for a rebate to be issued by the drug company—the exact arrangement HRSA had objected to before. Moreover, the announced Rebate Program was a "pilot" in name only; the Notice provided the program would cover all 14,600 covered entities and involve ten critical and common drugs. *See* Compl. ¶¶ 7, 56.

Despite recognizing that a change from an upfront discount to a rebate model could have a seismic, harmful effect on 340B hospitals, HRSA's Notice contained no serious justification or explanation for the Rebate Program. The Notice stated that HRSA had "received inquiries" from drug companies about implementation of new "Maximum Fair Prices" for certain drugs under the CMS Medicare Drug Price Negotiation Selected List. *See* 90 Fed. Reg. at 38165. But the Notice did not elaborate on why such a convoluted Rebate Program involving the transfer of hundreds of millions of dollars was needed to address deduplication concerns for that program. *See* Compl. ¶¶ 55, 58. It did not consider or address 340B providers' longstanding operational reliance on upfront discounts, nor the economic costs that would result from a sudden shift to a rebate model. *Id.* ¶¶ 57, 63–71. It also did not address the impact on patient care that would result from a move to a

rebate model. *Id*. ¶¶ 62, 71, 82–83, 107. Finally, the Notice did not consider any of the obvious and less costly alternatives to the proposed Rebate Program. *Id*. ¶¶ 56, 60, 87–91.

The Notice solicited comments, and Defendants received many—over 1,100 within the 31-day period. Commenters detailed the costs and burdens that the Rebate Program will impose on covered entities and their patients—none of which were discussed in the Notice. *See, e.g*., Ex. 8 at 13–14; Ex. 17 at 2–3; Ex. 21 at 1–2. Several commenters focused on the calamitous effects of cash-strapped covered entities having to float billions to the drug industry while waiting for their 340B discounts. *See, e.g.*, Ex. 18 at 6; Ex. 10 at 3; Ex. 14 at 1–2. Commenters flagged concerns with HRSA's chosen "Beacon" software platform. *See, e.g*., Ex. 16 at 11–12. Commenters submitted alternatives to the Rebate Program that would address the underlying concerns flagged by HRSA in its Notice. *See, e.g*., Ex. 8 at 5; Ex. 13 at 2. Commenters also highlighted less costly alternatives to the structure of HRSA's Rebate Program. *See, e.g*., Ex. 16 at 8; Ex. 17 at 3–4.

Defendants ignored all 1,100 comments. HRSA did not update its Notice, respond to comments in its online FAQs,[4] or take any other steps to address the many problems the public raised. As of the date of filing this Motion, HRSA has yet to address, among others: (a) HRSA's about-face on its position regarding the downsides of a 340B rebate model; (b) the staggering costs of the proposed rebate program; (c) the obvious, less burdensome alternatives that would address Defendants' stated goals; and (d) other obvious problems, from the lack of a functional dispute resolution process (a concern HRSA itself had raised in 2024) to the outrageous conditions imposed by the drug companies' chosen software vendor to the risks of implementing this Rebate Program on such a hurried timeline. Compl. ¶¶ 72–100; Golder Decl. ¶¶ 24–25, 29–33.

[4] After publishing the Notice, HRSA made a website about the Rebate Program on which it included Frequently Asked Questions (FAQs). *See* HRSA, *340B Rebate Model Pilot Program* (Nov. 2025), https://www.hrsa.gov/opa/340b-model-pilot-program. The FAQs, however, do not address any of the issues above. Compl. ¶ 60.

Rather than answer any of the 1,100 comments they received, Defendants have barreled ahead with the program, risking significant disruption to healthcare in Maine and across the country at the beginning of the new year. Between October 30 and November 14, 2025, HRSA approved the rebate program applications that were privately submitted by nine eligible drug companies for ten drugs. All ten drugs are high-volume, high-cost brand-name drugs, and if 340B providers' supply of these drugs is disrupted under the Rebate Program—for example, if safety-net providers cannot pay the new massive upfront costs—then patients' health and lives will be at risk. Compl. ¶ 62. All ten drugs will impose, in the prior words of HRSA, "significantly higher up-front costs for covered entities," Dkt. 41-1 at 18–19, *J&J*, No. 1:24-cv-03188, and "cause unprecedented disruption to the [340B] program," Dkt. 35-1 at 20, *Eli Lilly*, No. 1:24-cv-03220.

Defendants' operational roll-out of their Rebate Program has been alarmingly deficient, and the program is at significant risk of failure come January 1. On information and belief, Defendants have not even tested the software platform on which the entire Rebate Program relies. Golder Decl. ¶ 32. Likewise, they have ignored that the software operator is claiming the right to retain and monetize all data given to it by 340B providers, posing cybersecurity and data privacy risks (an issue HRSA flagged in its 2024 letters to drug companies). Compl. ¶¶ 44, 118–20.

Even before the Rebate Program takes effect, 340B providers, like Plaintiffs, are suffering harmful costs and disruptions. The prospect of multi-million-dollar financial outlays to drug companies is forcing 340B providers to pause key service improvements and projects, from providing new patient services to refreshing lifesaving equipment. Providers also are assuming new costs, including hiring personnel and vendors to handle the massive administrative burden associated with the Rebate Program. *See infra* pp. 16–19. Without immediate intervention by this Court, patients and 340B providers will irreversibly bear the costs of the unlawful Rebate Program.

## LEGAL STANDARD AND REVIEWABILITY

The purpose of preliminary relief is to "preserve the relative positions of the parties until a trial on the merits can be held." *Starbucks Corp. v. McKinney*, 602 U.S. 339, 346 (2024) (citation omitted). A district court may grant a temporary restraining order when a movant shows "(1) it is likely to succeed on the merits; (2) it is likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in its favor; and (4) an injunction is in the public interest." *Doe v. Trump*, 157 F. 4th 36, 46 (1st Cir. 2025) (cleaned up); *Monga v. Nat'l Endowment for Arts*, 323 F. Supp. 3d 75, 82 (D. Me. 2018) (temporary restraining order test same as for preliminary injunction). When the government is the opposing party, the balance-of-equities and public-interest factors merge. *See, e.g.*, *Nken v. Holder*, 556 U.S. 418, 435 (2009).

HRSA's 340B Rebate Program is reviewable under the Administrative Procedure Act ("APA") as a final agency action for which there is no other remedy. 5 U.S.C. § 704. The Rebate Program is set to take effect on January 1, and HRSA has already approved nine drug companies' rebate plans for ten drugs.[5] The hospital Plaintiffs, as well as many other 340B providers that belong to Plaintiffs AHA and MHA, are experiencing the program's "effects" in a very "concrete way," as they begin to bear costs of complying with the Rebate Program. *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 807–08 (2003) (citation omitted). The issues raised in this motion are ripe, and "the hardship" to Plaintiffs "of withholding court consideration" until later would be immense. *Saline Parents v. Garland*, 88 F.4th 298, 306 (D.C. Cir. 2023) (citation omitted).

## ARGUMENT

All four factors weigh heavily in favor of Plaintiffs. *First*, Plaintiffs are likely to succeed on the merits of their APA claims because, among other things: (a) Defendants' explanation for the

[5] Novartis Pharmaceuticals Corp.'s plan for the drug Entresto has also been approved, but for an April 1, 2026 start. *See* Compl. ¶ 105. There is therefore nothing magical about Defendants' January 1, 2026 deadline.

Rebate Program lacks sufficient justification and ignores the decades-long reliance interests on the upfront discount model; (b) Defendants ignored critical, material information raised in comments, thereby ignoring important aspects of the problem, including costs and benefits; and (c) Defendants disregarded reasonable alternatives. *Second*, Plaintiffs face severe, imminent, and irreparable harm in the absence of preliminary relief. In addition to imposing unrecoverable financial losses upon Plaintiffs, the Rebate Program now impairs both their operations and their ability to fulfill their missions of providing care to rural and underserved populations. *Finally*, the balance of the equities and the public interest support preliminary relief to protect public access to healthcare and pause Defendants' unlawful agency action.

## I. Plaintiffs Are Likely to Prevail on the Merits of Their APA Claims.

Plaintiffs will likely succeed on their claims because Defendants failed to follow basic principles of administrative law, which require consideration of reliance interests, material comments, costs, and less burdensome alternatives. Defendants also failed to address key issues they have raised about rebate models, including in 2024 letters to drug companies and court filings *this year*. An agency acts arbitrarily and capriciously, in violation of the APA, when it "entirely fail[s] to consider an important aspect of the problem, offer[s] an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm,* 463 U.S. at 43.

### A. *Defendants Offered No Justification for Abandoning the Upfront Discount Model and Ignored Decades of Reliance by Thousands of Healthcare Providers.*

Defendants have offered no reasonable explanation for instituting the Rebate Program. "[A]gency action [must] be reasonable and reasonably explained," *Prometheus Radio Project*, 592 U.S. at 423, and a "product of reasoned decisionmaking." *State Farm,* 463 U.S. at 52. Critically, when an agency reverses its prior policies, as here, the Supreme Court has held that the APA

requires "more detailed justification than what would suffice for a new policy created on a blank slate," particularly "when its prior policy has engendered serious reliance interests." *Fox Television Stations, Inc.*, 556 U.S. at 515. In explaining a policy change, the agency is "required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *Regents of the Univ. of Cal.*, 591 U.S. at 33.

Defendants devote, at most, a few sentences in their Notice to explaining the rationale for the Rebate Program. 90 Fed. Reg. 38165. The Notice claims Defendants are "introducing this pilot program to test the rebate model on a select group of drugs." *Id.* Though muddled in the Notice, the agency indicated a desire to address deduplication of discounts between the 340B and Medicare programs (*i.e.*, a way of ensuring two discounts are not applied to the same drug when only one is permitted).[6] Defendants never publicly supplemented their reasoning after issuing the Notice.

This barebones explanation falls far short of the reasoned decision-making demanded by the APA, because "statements of aspirational goals are not the same as reasoned explanations for why an action is chosen or how the chosen action will effectuate the stated goals." *Ass'n of Am. Univ. v. Nat'l Sci. Found.*, 788 F. Supp. 3d 106, 136 (D. Mass. 2025). Here, there is no discussion, for example, of why it is necessary to implement the program this way, what costs and benefits might be relevant, or how patients could be affected. "The reasoned explanation requirement" is "meant to ensure that agencies offer genuine justifications . . . that can be scrutinized by courts and the interested public." *Dep't of Com.*, 588 U.S. at 785. "The failure to provide any type of reasoning renders the [challenged] Notice arbitrary and capricious." *Massachusetts v. NIH*, 770 F. Supp. 3d 277, 306 (D. Mass. 2025).

[6] The Notice says that HRSA has received inquiries about proposed rebate models "primarily to address 340B and Maximum Fair Price (MFP) deduplication, but also to facilitate other aims such as the prevention of 340B Medicaid duplicate discounts and diversion." *Id.* (footnote omitted). The Notice does not, however, say the latter goals motivated the Rebate Program; in fact, Criterion #13 bars drug companies from denying rebates on those bases. *Id.*

Defendants' reasoning would be inadequate even if this were a new policy written on a blank state, but Defendants utterly failed to provide the "more substantial justification" required for a changed policy. *Mortg. Bankers Ass'n*, 575 U.S. at 106. Where, as here, an agency reverses itself, it must "show that there are good reasons for the new policy." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016). "In such cases it is not that further justification is demanded by the mere fact of policy change; but that a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy." *Id.* at 222. Defendants offered no such explanation here.

In proposing to abandon a 33-year policy, Defendants also made no examination of the reliance interests 340B hospitals have developed, how significant those interests are, and how those interests weigh against competing policy aims. *See Regents of the Univ. of Cal.*, 591 U.S. at 33. This absence is even more confounding since Defendants have acknowledged 340B providers' reliance on the upfront discount model this year. *See, e.g.*, Dkt. 35-1 at 19*, Eli Lilly,* No. 1:24-cv-3220 ("Covered entities generally preferred a discount system, because they could negotiate lower prices and needed less initial outlay of drug purchasing money."). This disregard of reliance interests further proves that Defendants violated the APA's most basic requirements.

### B. *Defendants Improperly Ignored Over 1,100 Comments Identifying Significant Problems with the Rebate Program.*

Defendants received over 1,100 comments identifying a multitude of problems with the Rebate Program and the negative ramifications it could have for the 340B Program. Defendants have not responded to a single comment, which is definitionally arbitrary and capricious.

In the Notice, Defendants stated that they were "under no obligation to respond to or act on the comments." 90 Fed. Reg. 38165. That is emphatically incorrect.[7] "[T]he failure to respond

[7] Tellingly, far as Plaintiffs can tell, a disclaimer about being under no obligation to respond or act on comments has

to significant comments . . . violates a substantive guarantee of the APA." *W. Coal Traffic League v. Surface Transp. Bd.*, 998 F.3d 945, 954 (D.C. Cir. 2021); *see also Marasco & Nesselbush, LLP v. Collins*, 6 F.4th 150, 169 (1st Cir. 2021) ("[E]ven if the rule is not subject to the notice-and-comment process, it is subject to review under the arbitrary and capricious standard."); *see generally Ohio*, 603 U.S. at 293, 298 (discussing substantive APA standards and holding that "EPA failed to address an important problem the public could and did raise during the comment period").

Aside from the Notice's revealing misstatement of the law, Defendants' silence in response to 1,100 comments proves they gave no adequate consideration to "important aspect[s] of the problem," *State Farm,* 463 U.S. at 43, particularly since these comments identified a host of problems with the Rebate Program. For example, commenters explained (a) that HRSA vastly underestimated the burdens that this program will impose on 340B hospitals, particularly as compared to the purported benefits; (b) that 340B providers could not be ready for a January 1 start date; (c) that there will be serious negative consequences for healthcare access, particularly in rural areas; (d) the absence of a functional dispute resolution mechanism; (e) that the chosen "Beacon" software platform is deeply flawed; and (f) that there are obvious, less burdensome alternatives. Compl. ¶¶ 72–100; Exs. 8–28. Total silence in response to this avalanche of identified problems makes this action straightforwardly unlawful.

### C. *Defendants Ignored the Scale of the Rebate Program's Costs, Including as Compared to Its Benefits.*

In promulgating the Rebate Program, Defendants ignored at least two types of significant monetary costs: (a) administrative costs and (b) costs associated with making full-price upfront payments to drug companies. Defendants also ignored critical non-monetary costs to patients and communities that will result from reduced access to healthcare. Given the magnitude of these costs,

never appeared elsewhere in the *Federal Register*.

Defendants' failure to appropriately consider them plainly violates the APA.

As the Supreme Court has held, "[a]gencies have long treated cost as a centrally relevant factor when deciding whether to regulate. Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages and the disadvantages of agency decisions." *Michigan v. EPA*, 576 U.S. 743, 752–53 (2015). A regulation is arbitrary and capricious "if the agency 'failed to consider an important aspect of the problem,'" which "includes, of course, considering the costs and benefits associated with the regulation." *Mexican Gulf Fishing*, 60 F.4th at 973 (quoting *State Farm*, 463 U.S. at 43). As part of its analysis, the agency must identify benefits that "bear a rational relationship to the . . . costs imposed." *Id.* Here, no such analysis happened for *any* of the significant costs inherent to the Rebate Program.

**Administrative Costs**: Neither the Notice nor the FAQs discussed the administrative costs to 340B providers. Defendants' only mention of administrative costs that has become public is in a memorandum they submitted to the Office of Management and Budget (OMB).[8] In that document, Defendants estimated the administrative burden on 340B providers to be $200,428,800 per year.[9] While a staggering amount in itself, the number grossly understates the true cost.

*First*, Defendants based their cost estimate on an assumption that covered entities will need to spend only two hours per week complying with the Rebate Program. This assumption appears to have been a wild guess that was never empirically evaluated. Defendants never explained how they arrived at that figure. They received a multitude of data in comments showing that compliance

[8] Under the Paperwork Reduction Act of 1995, HRSA was required to calculate the burden and time that would be expended by affected entities to generate, maintain, retain, disclose, or provide the data requested. 44 U.S.C. § 3506(c). HRSA did so in a Supporting Statement to an August 2025 Information Collection Request (ICR) submitted to OMB's Office of Information and Regulatory Affairs (OIRA). Ex. 30. In the ICR Supporting Statement, HRSA estimated the proposed Rebate Program would require covered entities to expend over *1.5 million hours* in 2026 to comply with the data collection requirements, which HRSA calculated would amount to over $200 million in costs. *Id.* at 6.

[9] To arrive at the figure, Defendants multiplied the (a) current number of covered entities (14,600), (b) an estimated 2 hours per week of compliance work, (c) 52 weeks in a year, and (d) the average hourly wage rate for pharmacists (as reported by Bureau of Labor Statistics data), totaling $200,428,800. *Id.*

would require much more than two hours per week, including that many covered entities would need to hire entirely new full-time staff to facilitate compliance. *See, e.g.*, Ex. 8 at 13–14; Ex. 17 at 2–3; Ex. 21. Defendants ignored this evidence that the $200 million was low by orders of magnitude, and they never updated their assessment of the administrative costs.

*Second*, Defendants never identified, evaluated, or quantified benefits that "bear a rational relationship" to costs imposed by the Rebate Program. *Mexican Gulf Fishing*, 60 F.4th at 973. Put differently, Defendants privately (under-)calculated a $200 million administrative cost but never explained why that cost, if true, would be worth any (uncalculated) benefits of the Rebate Program.

**Costs of Upfront Full-Price Payments**: Defendants' $200 million calculation exclusively focuses on administrative costs, but a rebate program imposes other significant costs: upfront payments for drugs. As Defendants wrote last year, "[a]s a result of this shift [to a rebate model], covered entities, including those which primarily serve rural and underserved populations, would need to pay significantly higher prices on prescription drugs at the time of purchase." Ex. 1 at -66; Ex. 4 at -292; Ex. 5 at -342; *see also* Ex. 18 at 6; Ex. 10 at 3; Ex. 14. The costs to 340B providers of paying significantly higher prices to drug companies is an issue that Defendants *never* address in the Notice or FAQs. Nor did they respond to comments showing those costs would amount to hundreds of millions.[10] There was no effort to quantify these upfront payment costs that Defendants have historically conceded would be significant (and would favor the discount model).

**Non-Monetary Costs**: Defendants also failed to address how the Rebate Program might impact patient care, the availability of life-saving drugs, participation in the 340B Program, or the long-term viability of 340B providers—all of which are affected by the dramatic increase in costs imposed by the Rebate Program. These non-monetary costs are relevant factors and "important

[10] For example, one commenter calculated that a set of 81 covered entities would have needed to float drug companies more than $348 million under the rebate model during the first half of 2025 had the program been in effect. Ex. 9.

aspect[s] of the problem." *State Farm,* 463 U.S. 29 at 43; Compl. ¶ 51 n.1.

**D. *Defendants Failed to Consider Any of the Significant, Viable, or Obvious Alternative Options and Improperly Sought a Predetermined Result.***

Several stakeholders submitted comments that identified alternatives to the Rebate Program that would address the underlying concerns flagged in the Notice. By ignoring these comments, Defendants "fail[ed] to consider 'significant and viable and obvious alternatives."' *Dist. Hosp. Partners*, 786 F.3d at 59 (citation omitted); *see Stauffer v. Internal Revenue Serv*., 285 F. Supp. 3d 474, 485 (D. Mass. 2017) ("the agency must explain why it rejected 'reasonably obvious' alternatives"); *Ass'n of Am. Univ. v. Dep't of Def*., 792 F. Supp. 3d 143, 170 (D. Mass. 2025). The proposed alternatives can be divided into two categories: (1) less burdensome alternatives to a rebate model that would address the reason why Defendants claimed the Rebate Program was necessary, and (2) less burdensome "pilot programs" that would avoid tens, if not hundreds, of millions of dollars in compliance and upfront payment costs over the next year. Defendants' failure to consider these alternatives constitutes unreasonable decision-making.

**Alternatives to the Rebate Model**: Commenters submitted several alternatives to the Rebate Program that would address HRSA's rationale for it. Compl. ¶¶ 87–88. To take just one example, Plaintiff AHA noted that IRA/340B deduplication could be done via a government-backed "clearinghouse" to exchange information between covered entities and drug companies, which would achieve the purported goal of this program without requiring safety-net hospitals to pay millions of dollars in administrative costs and full price upfront drug payments. Ex. 8 at 5; Ex. 13 at 2. In fact, Plaintiff AHA noted that CMS recently adopted the same "340B claims data repository" to address a similar IRA/340B deduplication concern. Ex. 8 at 5; Compl. ¶ 88. In fact, Defendants formally adopted that particular "clearinghouse" *right after* they approved drug company applications for the Rebate Program. Yet Defendants ignored this and other alternatives.

**Alternative Pilot Programs**: Commenters also highlighted less costly alternatives to the structure of HRSA's all-encompassing so-called "pilot" program. Compl. ¶¶ 89–91. They noted that HRSA should have begun with a more limited scope of covered entities, consistent with the past practice of federal healthcare agencies. For example, commenters noted that the Notice failed to consider whether the Rebate Program's goals could be achieved through a pilot program open to covered entity *volunteers*. Ex. 16 at 8. Alternatively, commenters proposed limiting the Rebate Program to Medicare Part D patients, who were the only ones at risk of duplication. Ex. 17 at 3–4. Commenters separately noted that a pilot could be narrowed to a smaller subset of drugs that would foist fewer administrative and upfront costs on safety-net providers. Ex. 16 at 8.

Any of these alternatives would have reduced the significant costs to 340B hospitals, as well as the concomitant risks to patient care. Yet Defendants ignored every possible alternative proposed and instead stormed forward with the Rebate Program without any notable change in design. Indeed, what is clear from the agency process—or lack thereof—is that Defendants never actually intended to, and did not, engage in an open-minded decision-making process. Instead, the outcome was predetermined by Defendants, such that they were "unwilling or unable to rationally consider counterarguments." *Dep't of Com.*, 351 F. Supp. 3d at 663; *see* Compl. ¶¶ 113, 167–73.

## II. Plaintiffs Will Suffer Irreparable Harm Without Immediate Injunctive Relief.

A plaintiff seeking preliminary relief must show "a cognizable threat" of "a substantial injury that is not accurately measurable or adequately compensable by money damages" and thus constitutes irreparable harm. *Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 102 F.3d 12, 19 (1st Cir. 1996). "District courts have broad discretion to evaluate the irreparability of alleged harm and to make determinations regarding the propriety of injunctive relief." *Id.* (citation omitted).

Defendants have implicitly conceded—both in interagency memoranda and federal court

filings—that covered entities will incur massive costs both from administrative burden and increased upfront payment costs. These costs extend to all individual Plaintiffs and other members of the organization Plaintiffs and have already begun in anticipation of the January 1 start date. In total, AHA estimates the Rebate Program will cost its members more than $400 million annually in administrative costs alone. Golder Decl. ¶¶ 28, 38. Individually, Plaintiff Dallas County Medical Center (DCMC) has to hire two full-time employees, one in the pharmacy department and another in accounting, to handle the Rebate Program. Mantz Decl. ¶ 18. Plaintiff Nathan Littauer Hospital (NLH) also is hiring a full-time employee exclusively for the Rebate Program, Fadale Decl. ¶ 22, and Plaintiff St. Mary's Regional Medical Center anticipates needing to do the same, Brown Decl. ¶ 21. All will face mounting costs leading up to and after January 1, and these costs will force diversion of critical resources to simply comply with the mandatory Rebate Program.

"Complying with an agency order later held invalid almost always produces the irreparable harm of nonrecoverable compliance costs." *Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1142 (5th Cir. 2021) (cleaned up). "The costs of complying with challenged regulations have been recognized as irreparable given the obstacles faced when suing for monetary damages," particularly "in the context of the APA, which does not allow for monetary damages." *California v. Kennedy*, __ F. Supp. 3d __, 2025 WL 2807729, at *6 (D. Mass. Oct. 1, 2025). Here, Plaintiffs will be unable to recover any of the costs that result from the Rebate Program, meaning they will be irreparably harmed.

By diverting 340B providers' operating capital to drug companies for unknown periods of time—with no enforceable guarantee of repayment—the Rebate Program has put covered entities in a period of financial stasis and retrenchment. Providers cannot undertake investments and service line expansions with this level of uncertainty—especially hospitals in Maine that, on

average, have extremely limited cash on hand. Austin Decl. ¶ 9. St. Mary's has explained that "[b]y cutting into our savings from the 340B discount program, the rebate program will force us to cut back or discontinue health-promoting services." Brown Decl. ¶ 18. DCMC, moreover, has been forced to delay critical maintenance on its hospital facilities and the construction of a ramp for disabled patients at its occupational therapy clinic due to the Rebate Program. Mantz Decl. ¶¶ 15, 20. And NLH has put its pharmacy build-out, which would ensure more patients get access to their medications consistent with the goal of 340B, on hold. Fadale Decl. ¶ 24. Each of these is an irreparable harm. *See Rhode Island v. Trump*, 781 F. Supp. 3d 25, 52 (D.R.I. 2025) (halting library services and forcing an entity into a hiring freeze constituted irreparable harm).

Finally, the Rebate Program will irreparably harm Plaintiffs by preventing them from carrying out their missions. The 340B Program is intended to allow covered entities to stretch their resources to provide more comprehensive care for the patients and communities, but the Rebate Program threatens to imminently constrict services, such as:

- St. Mary's' ability to reduce the price of some outpatient drugs for its patients and to offer an infusion therapy program in which eligible patients receive the drug for free. Brown Decl. ¶ 18. So too for other hospitals in Maine. Austin Decl. ¶¶ 11, 15.
- DCMC's recently opened cancer telehealth clinic, which spares patients from driving two hours to see the nearest oncologist. Mantz Decl. ¶¶ 12, 20.
- Unity Medical Center's recently opened cardiac and pulmonary rehabilitation services and patient access services. O'Neil Decl. ¶ 12.
- NLH's plan to expand its primary care services to a new location (for which it has been gifted property). Fadale Decl. ¶¶ 18, 24.

Illegal agency actions cause irreparable harm by forcing regulated parties to divert

resources away from their core mission or abandon vital programs. *See, e.g., Somerville Pub. Schs. v. McMahon*, 139 F.4th 63, 75 (1st Cir. 2025) (irreparable harm where "the challenged actions would jeopardize [plaintiffs'] ability to proceed with their programs"); *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 9 (D.C. Cir. 2016) (similar); *Mass. Fair Hous. Ctr. v. U.S. Dep't of Hous. & Urb. Dev.*, 496 F. Supp. 3d 600, 611 (D. Mass. 2020). That is exactly what will happen here. As a unanimous Supreme Court explained, "340B hospitals 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). The diversion of that funding, which is *already occurring* in advance of January 1, irreparably harms those valuable services and that mission.

### III. The Balance of the Equities Strongly Favors Plaintiffs and A Preliminary Injunction Serves the Public Interest.

For the final factor, courts "must balance the competing claims of injury and must consider the effect on each party [and the public] of the granting or withholding of the requested relief." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008) (citation omitted). Plaintiffs, their patients, and their communities face imminent injury from the diversion of resources that would otherwise go to healthcare for vulnerable patients. *See supra* pp. 18–19. In addition, it contravenes the public interest to interfere with patient care by impairing access to critical medications. *Rio Grande Cmty. Health Ctr., Inc. v. Rullan*, 397 F.3d 56, 77 (1st Cir. 2005) (affirming preliminary injunction requiring government payment to health center as in the public interest because "any shut down of [the clinic] would adversely affect hundreds of Medicaid patients"); *see also Mass. Ass'n of Older Ams. v. Sharp*, 700 F.2d 749, 753–54 (1st Cir. 1983) (harm from being "financially unable to obtain necessary medical treatment" held to "far outweigh[]" claimed harm to government of having to pay benefits that may not be owed); *e.g.*, Golder Decl. ¶¶ 33–39.

On Defendants' side, there is no public interest in continuing unlawful action. *Somerville*

*Pub. Schs.*, 139 F.4th at 76. "To the contrary, there is a substantial public interest in having governmental agencies abide by the federal laws that govern their existence and operations." *League of Women Voters*, 838 F.3d at 12 (cited in *Maine v. Dep't of Agric.*, 778 F. Supp. 3d 200, 236 (D. Me. 2025)). And Plaintiffs are seeking preliminary relief for its quintessential purpose: to maintain the status quo. *Starbucks Corp.*, 602 U.S. at 346. Defendants cannot credibly claim harm from keeping the upfront discount system they have endorsed for decades until this case resolves.

## IV. Plaintiffs Should Not Be Required to Post Any Substantial Bond.

Relief will "do the defendant[s] no material damage," such that the Court should "dispense with any security requirement." *Am. First Legal Found. v. Becerra*, 2024 WL 3741402, at *16 n.11 (D.D.C. Aug. 9, 2024). If the Court requires a bond, Plaintiffs respectfully request it be nominal, consistent with Court practice. *See Maine*, 778 F. Supp. 3d at 236–38 (collecting cases).

## CONCLUSION

This Court should grant Plaintiffs' motion for a temporary restraining order prohibiting the "340B Rebate Model Pilot Program" from going into effect until this Court enters a final judgment in this case and prohibiting Defendants from implementing the Rebate Program until the same. This Court should enter the order **before January 1, 2026** when the Rebate Program unlawfully forces safety-net providers to lose immense—potentially existential—amounts of unrecoverable capital that will impair health services to patients in Maine and across the country.

Dated: December 1, 2025

Respectfully submitted,

*/s/ Melissa A. Hewey*

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**Pro hac vice certification forthcoming.*
***Admitted in NY only; practice supervised by members of D.C. Bar. Pro hac vice application forthcoming.*

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

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| THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,<br><br>Plaintiffs,<br><br>v.<br><br>ROBERT F. KENNEDY, JR. Secretary of the U.S. Department of Health and Human Services, ET AL.,<br><br>Defendants. | Case No.<br><br>**DECLARATION OF JEFFREY AUSTIN IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER** |

I, Jeffrey Austin, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am the Vice President, Government Affairs and Communications of the Maine Hospital Association ("MHA"), which is a non-profit representing 32 community-governed hospitals in Maine. I submit this declaration in support of Plaintiffs' motion for a temporary restraining order. The facts in this declaration are based on my personal knowledge and experience, and my review of MHA's business records.

2. I joined MHA in 2010. As Vice President, Government Affairs and Communications, I am responsible for MHA's advocacy activities at the state and federal levels, and for all of the Association's communications.

3. Before joining MHA, I was a government affairs professional for the Maine Municipal Association. I earned my undergraduate degree from Notre Dame and my law degree from Boston College.

4. Founded in 1937, MHA is the primary advocate for Maine hospitals in the Maine State Legislature, the U.S. Congress, and state and federal regulatory bodies. MHA also provides educational services and serves as a source of information about issues impacting healthcare in Maine for our hospital members, lawmakers, and the public. Our mission is to provide leadership through advocacy, information, and education to support our members in fulfilling their missions to improve the health of their patients and communities they serve.

5. Currently, 26 of MHA's 32 member hospitals participate in the 340B drug discount program.

6. I am familiar with the current 340B discount program and Defendants' plan to replace the 340B program's discount model with a rebate program starting on January 1, 2026, for nine popular drugs. I also am familiar with the harm that this switch to a rebate program will cause MHA's members if the rebate program is not temporarily enjoined before January 1.

**MHA's Membership**

7. MHA's members provide essential, around-the-clock medical care across the State of Maine. Half of our hospital members are critical access hospitals, meaning that they are small acute care facilities and have limited services and no more than 25 inpatient beds.

8. Our members face particular challenges in providing healthcare in a largely rural state, and four Maine hospitals have closed within the past decade (Inland Hospital in Waterville, St. Andrews in Boothbay, Parkview Hospital in Brunswick, and Goodall Hospital in Sanford). Other hospitals have had to shut down certain services, including 10 closures of labor and delivery units within the past decade.

9. Earlier this year, MHA hired PYA Accountants and Advisors to review the financial conditions of Maine's hospitals. PYA found that 94% of Maine's hospitals were at a medium or

high risk of closure based on their 2023 financial metrics. PYA's study also found that the median number of days of cash on hand for Maine's hospitals was less than 10.6.

**Benefits of the 340B Discount Program to MHA's Members and Mainers, and Threatened Harm from Defendants' Proposed Rebate Program**

10. MHA's 26 members that participate in the 340B discount program receive a collective benefit of an estimated $250 million per year from the program.

11. Our members put these savings from the 340B program back into their communities through activities such as financial assistance to patients who cannot afford care; community-based health clinics at schools, nursing homes, and other easy-to-access locations; outbreak preparedness programs; and life-saving opioid intervention services (such as the provision of naloxone, suboxone, and methadone).

12. The 340B discount program is essential to our members' ability to provide these programs. Given the very limited cash on hand that most of our members have, it is not feasible for them to pay the expensive wholesale acquisition cost of drugs upfront and wait for reimbursement.

13. The 340B discount program is also essential for our members' overall operating margins. If the program were discontinued or interrupted, our 26 participating members' estimated aggregate operating margin would fall steeply to negative $220 million.

14. I have spoken with member hospitals and they have expressed serious concerns about the rebate program, including their inability to fund the administrative costs necessary to comply with it; their inability to float large sums of money to drug companies before receiving rebates; the impact on their ability to provide comprehensive patient services; the one-sided nature of the Beacon software platform; the absence of a meaningful dispute resolution process; and the impending January 1 start date that many cannot meet.

15. Maine's hospitals are already facing very difficult financial conditions as they strive to continue providing a full range of care to their communities. Defendants' 340B rebate program threatens to put further financial stress on our state's healthcare system, which we cannot absorb without adverse impacts to our communities.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed this 26th day of November, 2025 at Augusta, Maine.

*/s/ Jeffrey Austin*

Jeffrey Austin

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

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| THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,<br><br>Plaintiffs,<br><br>v.<br><br>ROBERT F. KENNEDY, JR. Secretary of the U.S. Department of Health and Human Services, ET AL.,<br><br>Defendants. | Case No.<br><br>**DECLARATION OF WINFIELD S. BROWN IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER** |

I, Winfield S. Brown, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am the President of St. Mary's Regional Medical Center ("St. Mary's") and a Senior Vice President of Covenant Health. I became President of St. Mary's on October 1, 2024, and am responsible for the health system's operations and finances. I submit this declaration in support of Plaintiffs' motion for a temporary restraining order. The facts in this declaration are based on my personal knowledge and experience, and my review of St. Mary's business records.

2. I have worked in healthcare administration for nearly 30 years. I previously served as Executive Director and Vice President of the St. Mary's Foundation from 1996 to 2003. In this role, I directed the health system's philanthropic efforts, volunteer services, and community programs. I also have served as Vice President, Administration for Lowell General Hospital and as President and Chief Executive Officer for Heywood Healthcare, both in Massachusetts. Immediately before rejoining St. Mary's, I served as Interim Chief Executive Officer of Mt. Ascutney Hospital and Health Center, a member of Dartmouth Health.

3. I earned my Bachelor of Arts in Economics from Bates College, my Master of Healthcare Administration from the University of Minnesota, and my Master of Science in Business from Husson University. I am a Fellow in the American College of Healthcare Executives, a professional society of more than 50,000 leaders in healthcare.

4. I am familiar with Defendants' plan to replace the 340B program's current discount model with a rebate program starting on January 1, 2026, for nine popular drugs. I also know the harm that this switch to a rebate program will cause St. Mary's if allowed to go into effect next month.

**St. Mary's Provides Critical Care to an Underserved Population of Mainers**

5. St. Mary's has been caring for the people of Maine for more than 135 years, founded by the Sisters of Charity in 1888. Based in Lewiston, Maine, with additional provider practices in Auburn and Poland, St. Mary's serves the second largest metro area in Maine, with a population of approximately 100,000 individuals.

6. Defendant Health Resources and Services Administration has designated St. Mary's' home, Androscoggin County, as a medically underserved area.[1] Lewiston's poverty rate exceeds Maine's,[2] and many of St. Mary's patients are low income. Data from the 2020 census shows that that nearly twenty percent of the Lewiston-Auburn population lives in poverty; more than fifteen percent are disabled and under the age of 65, and nearly seven percent of the population is under the age of 65 and uninsured. St. Mary's is proud to dedicate its resources to serving the entire community.

[1] Health Res. & Servs. Admin., *MUA Find*, https://data.hrsa.gov/tools/shortage-area/mua-find (last visited Nov. 21, 2025).

[2] U.S. Census Bureau, *Lewiston, ME*, https://data.census.gov/profile/Lewiston_city,_Maine?g=160XX00US2338740#income-and-poverty.

7. St. Mary's offers a range of essential healthcare, including emergency department services, urgent care, inpatient chemical and alcohol detox, cardiology services, surgical and post-surgical care, pediatric care, neurological care, gynecological care, orthopedics, physical therapy, occupational therapy, speech therapy, and primary care. Our medical center also operates d'Youville Pavilion, which is a 210-bed senior care facility for seniors providing post-acute rehabilitation, long-term care, and memory care.

8. As part of our acute care community hospital in Lewiston, St. Mary's also operates the only behavioral health emergency department in the entire state of Maine, providing critical care for often severely compromised patients.

9. St. Mary's also is the only local provider of acute behavioral and mental health care services. The community relies on these critically important services, especially in the wake of the mass shooting in Lewiston in October 2023.

10. Because of these critical, unique behavioral health services and our detox services, St. Mary's has been designated by Defendant Department of Health and Human Services as an "Essential Community Provider" that serves "primarily low-income and medically underserved populations."[3]

11. Approximately 67% to 75% of St. Mary's patient population has historically received insurance coverage through Medicaid or Medicare. St. Mary's is classified as a "disproportionate share hospital" because it treats a significant number of low-income patients.

12. Many of our patients have no access to private transportation and, given the difficulty of traveling in Maine during the winter months, cannot feasibly visit multiple facilities or pharmacies to get the medical care and prescriptions they need.

[3] *HHS Rolling Draft Essential Community Provider (ECP) List for the Federally-facilitated Marketplace*, Ctrs. for Medicare & Medicaid Servs., https://data.healthcare.gov/rolling-draft-list (last visited Nov. 21, 2025).

**St. Mary's Cannot Absorb the Increased Costs of Defendants' Rebate Program**

13. Defendants' rebate program threatens imminent harm to the patients and community that St. Mary's serves.

14. St. Mary's' present cash-on-hand is limited, which means our liquidity is a key operational consideration. St. Mary's does not have the funds to pay exorbitant upfront costs of medications and wait for drug companies to reimburse us.

15. Our health system has not had a positive operating margin since before the COVID-19 pandemic. Last year, we had an operating loss of approximately $4 million. St. Mary's is projecting a comparably substantial loss this year.

16. St. Mary's has already had to close some of our services in recent years. For example, the health system no longer has an obstetrics unit and therefore cannot deliver babies.

**The Rebate Program Will Cause Harm to St. Mary's and Its Patients If Allowed to Proceed**

17. St. Mary's has participated in the 340B program since 2002. We currently save approximately $3.3 million annually through the 340B discount program.

18. Our savings from the 340B discount program help St. Mary's to provide health-promoting programs to our community regardless of patients' ability to pay. For example, the program allows St. Mary's to reduce the price of some outpatient drugs for its patients. In addition, the program allows St. Mary's to offer an infusion therapy program in which eligible patients receive the drug completely free of charge. The program further allows St. Mary's to provide behavioral health services without regard to patients' ability to pay, and various community health-promoting events. By cutting into our savings from the 340B discount program, the rebate program will force us to cut back or discontinue health-promoting services like these.

19. St. Mary's administers five of the drugs slated for Defendants' Rebate Program: Eliquis, Jardiance, and Xarelto on an inpatient basis; and Januvia, Novolog, and Jardiance from a contract pharmacy.

20. Defendants' rebate program will create significant cash flow challenges for St. Mary's because of the new requirement to pay wholesale acquisition cost for drugs upfront. We have limited cash-on-hand, making any additional outlay problematic. This problem is compounded by that fact that Defendants have not specified the consequences for drug companies that do not reimburse hospitals within ten days or that inappropriately deny rebates. I worry that St. Mary's' reimbursements will be delayed or denied without available recourse to Defendants.

21. St. Mary's is a leanly staffed health system, and we do not currently have staff capacity to comply with Defendants' rebate program to track the status of the refunds St. Mary's is owed from the drug companies. This process will take our health system significantly more than two hours per week; I expect that St. Mary's will have to hire a new staff person if the rebate program is implemented. We do not anticipate being able to hire and train a new staff person by January 1, 2026.

22. St. Mary's also is concerned that it must submit data to Beacon, a private third-party, on unreasonable take-it-or-leave-it terms, to access the 340B price of drugs included in the Rebate Program. We take patient privacy and data security very seriously, and our concerns are amplified by our understanding that Beacon is asserting the right to monetize this patient data and retain it even if the rebate program is discontinued. We would not ordinarily agree to such one-sided terms unless, as here, we were being forced to do so by the Defendants so that we can obtain our 340B discounts.

23. At bottom, the 340B rebate program will undermine the very mission of St. Mary's, to provide healthcare to the underserved in our region. We have been dedicated to this cause for over 135 years, and every dollar diverted by Defendants' 340B rebate program from fulfilling our mission risks devastating medical consequences to patients in our community.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed this 30th day of November, 2025 at Cumberland, Maine.

*/s/ Winfield S. Brown*

Winfield S. Brown

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

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| THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,<br><br>Plaintiffs,<br><br>v.<br><br>ROBERT F. KENNEDY, JR. Secretary of the U.S. Department of Health and Human Services, ET AL.,<br><br>Defendants. | Case No.<br><br>**DECLARATION OF SEAN M. FADALE IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER** |

I, Sean M. Fadale, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am the President and Chief Executive Officer of Nathan Littauer Hospital and Nursing Home ("NLH") and have served in this role since October 2020. As President and CEO of NLH, I am responsible for the tactical and strategic direction of Nathan Littauer's hospital, ambulatory clinics, and nursing home—which includes focus on the delivery of high-quality care in the safest environment possible. I am also responsible for the financial well-being of NLH, which is being compromised by Defendants' planned rebate program. I submit this declaration in support of Plaintiffs' motion for a temporary restraining order. The facts in this declaration are based on my personal knowledge and experience, and my review of NLH's business records.

2. I first started working in healthcare as a physical therapist. After 11 years as a clinician, I transitioned to the administrative side of healthcare and have served in leadership roles at hospitals in New York, Illinois, and Pennsylvania. I most recently served as CEO of Community Memorial Hospital in Hamilton, New York for eight years before joining NLH.

3. I have spent the majority of my career working in rural healthcare and am a member of the American Hospital Association's Rural Health Council. I am also a Fellow in the American College of Healthcare Executives, and a Board Member of the Iroquois Healthcare Association of New York and of the Hospital Association of New York State.

4. I earned my bachelor's degree in sports medicine from Mercyhurst University, and my master's degrees in physical therapy and business administration from Gannon University.

5. I am familiar with Defendants' plan to replace the 340B program's current discount model with a rebate program starting on January 1, 2026, for nine popular drugs. I also know the harm that this switch to a rebate program will cause NLH if it is not prevented from taking effect.

**NLH Provides Crucial Care to a Rural and Underserved Community**

6. NLH is the principal provider of acute and primary care for rural Fulton and Hamilton Counties, New York, and we operate the only remaining non-profit nursing home in our area.

7. NLH's 74-bed acute care hospital provides emergency services, general surgery, general inpatient services, and a number of specialty services, including cardiology, neurology, gastroenterology, obstetrics and gynecology, pediatrics, orthopedics, ophthalmology, and urology.

8. Our 84-bed nursing home provides around-the-clock skilled nursing care to short- and long-term residents, along with medical care, appropriate specialty care, and rehabilitation services, including physical therapy, occupational therapy, and speech therapy as needed.

9. NLH also operates 11 outpatient clinics in Amsterdam, Broadalbin, Caroga Lake, Fonda, Gloversville, Johnstown, Kingsboro, Mayfield, Perth, and Speculator, New York. These clinics provide primary care and, in some cases, specialist, laboratory, and pharmacy services.

Three of them (in Amsterdam, Gloversville, and Speculator) additionally serve as urgent care clinics with walk-in availability.

10. NLH also offers a Rural Nurse Residency Program to help train the next generation of nurses to serve rural communities.

11. Our patient population is primarily low-income and elderly. A significant number of our patients are retired from factory work in the leather tanning or needle trade industries. Diabetes and chronic obstructive pulmonary disease (COPD) are prominent drivers of poor health in our community.

12. Approximately 50% of all NLH patient care that is paid for has historically been paid for by Medicare or Medicaid. NLH has been designated as a "disproportionate share hospital" because it treats a significant number of low-income patients. NLH is also a Medicare Dependent Hospital, given our high number of Medicare patients in our service area.

**NLH Cannot Afford the Increased Costs of Defendants' Rebate Program**

13. Defendants' rebate program threatens imminent harm to the patients and community that NLH serves.

14. NLH does not have extra funds to pay significantly higher upfront costs on medications and wait for drug companies to reimburse it. This program will have a significantly negative impact on cashflow for NLH.

15. NLH has not had a positive operating margin since before the COVID-19 pandemic and has been using its pre-pandemic savings to cover its operating losses. The pandemic caused particular staffing challenges for NLH, and our labor costs have increased as we have had to replace providers, including with some travel nurses who do not live in our rural community long-

term. For the past few years, NLH's expenses have exceeded its revenue by more than $10 million. We project that we will operate at a loss of several million dollars this year.

**Defendants' Planned Rebate Program Will Cause Harm to NLH and Its Patients**

16. NLH has participated in the 340B program since 2012.

17. NLH currently saves approximately $1.4 million per year through the 340B discount program.

18. We used our accumulated prior savings from the 340B program to open our primary care health center in Broadalbin in 2019 and our center in Caroga Lake in 2021. These two small health centers are now able to address previously unmet needs in their respective communities. By cutting into our savings from the 340B discount program, the rebate program will force us to slow or stop the expansion of access to care in the Fulton and Hamilton County communities and restrict our abilities to update our facilities and equipment.

19. We also use our 340B program savings to support our general patient care operations, including financial assistance for uninsured patients who are unable to pay for their care, patient navigation services, and additional programs to help address patient social determinants of health challenges.

20. NLH administers seven of the drugs selected for participation for Defendants' rebate program: Eliquis, Enbrel, Farxiga, Januvia, Jardiance, Novolog, and Xarelto.

21. The shift to a rebate program will create major cash flow challenges for NLH because of the new requirement to pay wholesale acquisition cost for these drugs upfront and then wait for reimbursement. Even having to pay out significant amounts of money for a short period will adversely impact NLH's operations because, while it is with the drug companies, that cash will not be available for NLH's other expenses. But I am also concerned that the drug companies

will not reimburse NLH within 10 days because Defendants have not set out clear consequences for late or unfairly denied rebates. Particularly because NLH is a small hospital, I worry that we will be unevenly matched with drug companies in any dispute and that we will have little recourse from Defendants for getting the rebates that NLH is entitled to. It may prove to be unfeasible for NLH to participate in Defendants' rebate program, such that our clinicians would have to stop prescribing the participating drugs.

22. NLH's pharmacy staff currently coordinates our participation in the 340B program, including when NLH is eligible to purchase a new shipment of a medication at 340B discount pricing. Our pharmacy staff does not have capacity to administer Defendants' planned rebate program. NLH will be hiring a new full-time employee to handle this new administrative burden. Our third-party administrator also is still evaluating what changes its software will require to comply with Defendants' rebate program, and NLH may need to make additional direct payments to outside vendors to make changes in its technology. Given the timing of Defendants' announcements and the limited implementation information that has been provided, it is not feasible for NLH to be fully prepared for Defendants' rebate program on January 1, 2026.

23. NLH also is concerned that Defendants' rebate program requires hospitals to submit new categories of data to drug companies through a third-party platform (Beacon) chosen by the pharmaceutical industry. In order to continue participating in the 340B program as to seven popular drugs that NLH administers, we must agree to unreasonable take-it-or-leave-it terms that Beacon can change again at any time (including terms that claim to grant Beacon broad use of our deidentified patient-specific data for uses not necessary to the rebate program), and grant a broad waiver of liability to Beacon. Again, it seems that the way Defendants have designed their program provides NLH little to no recourse if Beacon improperly uses our data or does something else

wrong. We would not ordinarily agree to such one-sided terms unless, as here, we were being forced to do so by the Defendants so that we can obtain our 340B discounts.

24. The looming implementation of Defendants' rebate program has forced NLH to make major adjustments to its strategic plan. While we had been planning for five years in the future, we have had to scale back our strategic plan to two years at a time. NLH also has had to pause important projects, including the development of a new primary care clinic (for which NLH has already been gifted property) and the build-out of an adequate retail pharmacy, because of the uncertainty caused by Defendants' rebate program.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed this 26th day of November, 2025 at Gloversville, New York.

*/s/ Sean M. Fadale*

Sean M. Fadale

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

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| THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,<br><br>Plaintiffs,<br><br>v.<br><br>ROBERT F. KENNEDY, JR. Secretary of the U.S. Department of Health and Human Services, ET AL.,<br><br>Defendants. | Case No.<br><br>**DECLARATION OF CHAD GOLDER IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER** |

I, Chad Golder, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am the General Counsel and Secretary of the American Hospital Association ("AHA"), which is a non-profit association of healthcare organizations and individuals that are committed to improving the health of their communities. I submit this declaration in support of Plaintiffs' motion for a temporary restraining order. The facts in this declaration are based on my personal knowledge and experience, and my review of the AHA's business records.

2. I became General Counsel and Secretary of the AHA on January 1, 2024, after previously serving as the Association's Senior Vice President and Deputy General Counsel.

3. Before joining the AHA, I was a Partner and founding member of Munger, Tolles and Olson LLP's Washington, D.C. office. I also have spent a significant portion of my career in government service, as a Deputy Associate Attorney General, an Assistant U.S. Attorney in the Eastern District of Virginia, counsel to the Deputy Attorney General, and a law clerk to Justice John Paul Stevens of the U.S. Supreme Court and Judge Merrick Garland of the U.S. Court of

Appeals for the District of Columbia Circuit. I earned my undergraduate and law degrees from Yale University.

4. Founded in 1898, the AHA leads, represents, and serves nearly 5,000 member hospitals, health systems, and other healthcare organizations and 43,000 individual members with the mission of advancing the health of all individuals and communities. Through our representation and advocacy, the AHA ensures that our members' perspectives and needs are heard in national health policy development, legislative, and regulatory debates.

5. More than 2,000 of the AHA's member hospitals and health systems participate in the 340B drug pricing program. These members include disproportionate share hospitals that serve a high number of low-income patients. Many of these members operate on very thin (or negative) margins.

6. I am familiar with the current upfront discount model for the 340B program, drug companies' prior attempts to change that model, and Defendants' current plan to replace the 340B program's discount model with a rebate program starting on January 1, 2026, for nine popular drugs. I submitted comments in opposition to this plan on the AHA's behalf. I also am aware of the harm that this switch to a rebate program will cause the AHA's mission and many of its members if the rebate program is not temporarily enjoined before January 1.

**Defendants' Rebate Program Mandates Participation from the AHA's Members**

7. On July 31, 2025, Defendant Health Resources and Services Administration ("HRSA") announced a new "340B Rebate Model Pilot Program." I understand from the AHA's members that this announcement was made without meaningful consultation with 340B hospitals.

8. Under Defendants' rebate program, beginning January 1, 2026, 340B covered entities are required to purchase nine popular drugs at commercial prices, known as the full

Wholesale Acquisition Cost ("WAC"), and then apply for a rebate after dispensing the purchased drugs to a 340B-eligible patient.

9. The WAC is the "list price" for wholesalers—without any discounts or promotions. I understand from discussions with our members that the WAC is typically several times more expensive than the 340B price and that the WAC for some drugs slated for participation in Defendants' rebate program is more than 100 times the 340B price. Per 340B's implementing regulations, the "ceiling price" for 340B covered entities for name brand drugs (like all of those in Defendants' rebate program) must be set using the Average Manufacturer Price (inclusive of discounts) minus the Unit Rebate Amount (which is currently a minimum of 23.1%).[1]

10. Several of the drugs slated for participation in Defendants' program cost thousands of dollars for a 30-day supply. For example, one 30-day supply of Enbrel is $7,106, Stelara is $13,836, and Imbruvica is $14,934.[2] I understand that, based on a sample of 81 covered entities, The Craneware Group estimated in a comment submitted to HRSA that having to pay WAC upfront would increase those covered entities' actual spend on 340B drugs by more than five times.[3] Many members have informed me that having to pay those prices before receiving rebates will require a significant outlay of their operating capital or cash reserves.

11. Defendants' self-titled "pilot" rebate program is mandatory for covered entities that prescribe any of the drugs for which HRSA has approved rebate program applications. Therefore, all or nearly all of the AHA's more than 2,000 members who participate in the 340B program will be required to participate in the rebate program.

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[1] *See* 42 C.F.R. § 10.10(a); 340B Health, "340B Drug Pricing Program Overview," https://www.340bhealth.org/members/340b-program/overview/.

[2] *See* Ctrs. for Medicare & Medicaid Servs., "Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026," https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf.

[3] Comment ID HRSA-2025-0001-0076 on the 340B Program Notice (Federal Register No. 2025-14998).

**The AHA's Comments on Defendants' Rebate Program**

12. Given the importance of the 340B program to our mission of advancing the health of all individuals and communities, the AHA welcomed the opportunity to comment on Defendants' proposed rebate program.

13. On August 8, 2025, the first day of the comment period, the AHA (along with America's Essential Hospitals, the American Society of Health-Systems Pharmacists, the Association of American Medical Colleges, the Catholic Health Association of the United States, and 340B Health) submitted a comment requesting that Defendant Engels extend the period for comments on the proposed rebate program to September 15 and simultaneously extend the deadlines for drug company rebate plan submissions until October 20 and plan approvals until November 3.[4] We explained that the existing timeline, which provided only one week between the close of comments and drug company plan submissions, made it "impossible for the agency to meaningfully consider, in just seven days, all the feedback it will surely receive."

14. Defendants did not extend the comment deadline or, as far as I am aware, otherwise respond to our comment or any other comments.

15. On August 27, 2025, I submitted another comment on behalf of the AHA's more than 2,000 member hospitals and health systems that participate in the 340B drug pricing program in order to express the AHA's serious concerns with Defendants' proposed program.[5] Given that Defendants' conduct to date had indicated an intent to move forward with their proposed program regardless of the public comments, our comment addressed both why the program should not

[4] Comment ID HRSA-2025-0001-0005 on the 340B Program Notice (Federal Register No. 2025-14998).
[5] Comment ID HRSA-2025-0001-0052 on the 340B Program Notice (Federal Register No. 2025-14998) (the "AHA Comment").

proceed and what measures must be put in place to minimize the harm it will cause the AHA's members if it does proceed.

16. In the absence of any clearly articulated rationale from HRSA about its reason for shifting to a rebate program, the AHA's comment addressed arguments advanced by drug companies that 1) there is supposedly insufficient oversight of the safety-net healthcare providers participating in the 340B program and 2) drug companies purportedly cannot comply with the Inflation Reduction Act and 340B statute without a rebate model. AHA Comment at 10-11.

17. First, we explained that HRSA's own 340B audit data belies any claim of widespread program integrity concerns at covered entities; for example, HRSA's audits in Fiscal Year 2022 found that 75% of audited drug companies needed to make repayments to hospitals, while only 28% of audited hospitals needed to make repayments to drug companies. *Id.* at 10. We also noted that HRSA already audits participating hospitals at about 10 times the rate it audits participating drug companies. *Id.*

18. Second, we explained that one singular reference to the 340B non-duplication of discounts requirement in the Inflation Reduction Act does not require the upending of a discount model that hospitals have relied upon for more than 30 years. *Id.* at 10-11.

19. Our comment noted that large bipartisan groups of congresspeople had written to the Secretary of Health and Human Services in opposition to a rebate model, including after the passage of the Inflation Reduction Act. *Id.* For example, on September 27, 2024, nearly 200 members of Congress urged HRSA not to approve a rebate model put forth by Johnson & Johnson:

> We write to express our concern over the Johnson & Johnson (J&J) plan to upend more than 30 years of federal law by delaying access to 340B Drug Pricing Program (340B) discounts on pharmaceuticals for certain safety-net hospitals. . . . [We] urge you to use every enforcement tool at your disposal to protect the communities safety-net hospitals serve from this devastating change to 340B. . . .

> This [rebate] model would reduce resources available for providing comprehensive services to patients and communities, undermining the core purpose of 340B. . . .
>
> A rebate model would create significant financial challenges for safety-net hospitals, which already are operating under much lower operating margins than non-340B hospitals. . . .
>
> Many hospitals also would be forced to hire new full-time employees to develop new purchasing arrangements as well as to monitor, validate, and reconcile the rebates. Moreover, there is no existing infrastructure for accumulating and sharing the data that J&J would require for hospital rebate claims.[6]

20. Our comment also explained that drug companies could comply with the Inflation Reduction Act and 340B's longstanding discount model by simply making the maximum fair price for Medicare negotiated drugs available prospectively as is currently done for drugs purchased under the 340B program. AHA Comment at 11. Hospitals could then purchase Medicare negotiated drugs at either the drug's maximum fair price under the Inflation Reduction Act or 340B price, whichever price is lower for that particular drug.

21. Moreover, our comment detailed the significant harm that Defendants' rebate model would cause our members and their patients. As discussed further below, the AHA explained that Defendants' proposed program would limit our members' ability to provide community benefits and to fund critical patient services, put our members at risk of violating their bond covenants, and create expensive administrative burdens. *Id.* at 12-14.

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[6] Letter to Sec'y Becerra from A. Spanberger et al. (Sept. 27, 2024), 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.

Since the AHA's comment was submitted, I have seen that a group of more than 160 members of Congress from both parties have also written to Secretary Kennedy to express concerns that Defendants' proposed rebate program "threaten[s] 340B providers' ability to provide care and to keep their doors open to serve low-income communities." Letter to Sec'y Kennedy from D. Matsui et al. (Sept. 8, 2025), https://matsui.house.gov/sites/evo-subsites/matsui.house.gov/files/evo-media-document/20250909-matsui-final-letter-to-hhs_340b-rebate-model-pilot.pdf.

22. If Defendants were to proceed with their planned rebate program, our comment raised that the requirement for drug companies to reimburse "all costs for data submission through an Information Technology (IT) platform" did not come close to covering all of our members' costs to shift to a rebate model. *Id.* at 2-3. We urged Defendants to clarify that drug companies must timely pay all of covered entities' costs involved in the model switch, including increased staffing costs, additional payments to third-party vendors who manage data flows, and potential legal costs in forcing drug companies to comply with the program. *Id.*

23. The AHA's comment also urged Defendants to establish strict enforcement guidelines for drug company non-compliance given that failures to reimburse covered entities constitute impermissible overcharges for medications under 340B's statutory scheme. We pointed out that HRSA's notice and existing online FAQs did not provide sufficient guidance on how HRSA would determine non-compliance or when it would impose a penalty on a drug company for non-compliance. *Id.* at 3-4.

24. Similarly, our comment stressed the need for Defendants to create a dedicated process to solve rebate disputes because of the grave impacts that delays or denials of rebates would have on many of our members' finances. *Id.* at 5-6. We explained that the existing 340B alternative dispute resolution process would not work for Defendants' planned rebate program because of its statutory amount in dispute limits and the extended length of time that the process typically takes (during which period a covered entity would likely be deprived of significant amounts of money it is owed). *Id.* We asked HRSA to create a dispute resolution process that includes, at minimum, a designated human point of contact to receive complaints and a specific timeline for when complaints will be addressed. *Id.* at 6. And to assist in the resolution of disputes,

we also asked that drug companies be required to provide non-conclusory, evidence-based denials of rebates with specific drug company contact information.[7] *Id.*

25. We additionally pointed out that the Beacon platform selected by drug companies is a wholly owned subsidiary of the Berkeley Research Group, which has long been affiliated with drug companies and their trade association. *Id.* at 4-5. We also flagged that Defendants' planned program lacked strict guidelines on how our members' data could be used by Beacon and the drug companies. *Id.* at 5.

26. The AHA advocated for HRSA to engage a single, neutral, *third-party* entity to serve as a clearinghouse for any data submissions required under Defendants' rebate program. We brought to the agency's attention that the Centers for Medicare & Medicaid Services 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 and suggested that HRSA could use the same repository for the rebate program. *Id.* at 5. This alternative would minimize some of the administrative burden on our members by allowing them to submit claims data to one entity, limit the ability of drug companies to use data for other reasons, and allow HRSA to more easily oversee its program.

27. Finally, our comment asked HRSA to explain the criteria it plans to use to assess the success or failure of its self-titled "pilot" rebate program and to appropriately weigh the costs and administrative burdens of even a single improper rebate delay or denial in its assessment, given the grave stakes for our members of losing their 340B savings and having to spend more money just to continue participating in the program. *Id.* at 7.

[7] We also asked the agency to clarify that drug companies cannot deny rebates based on their unilaterally imposed contract pharmacy restrictions. *Id.* at 6-7.

28. On September 12, 2025, pursuant to the Paperwork Reduction Act of 1995, HRSA published a notice regarding an Information Collection Request that included HRSA's estimate of the administrative burden its rebate program would put on covered entities.[8] HRSA estimated that its rebate program would require two hours of work per week for each entity. On September 30, 2025, I submitted a comment in response on behalf of the AHA.[9] I explained that our members believe HRSA had severely underestimated the time burden of its program: the AHA's members anticipate that Defendants' rebate program will require them to "devote, on average, up to two full-time equivalents to manage the entire rebate model process," amounting to 80 hours per week—many multiples of Defendants' estimate of two hours. Our comment also explained that our members projected their administrative costs for the rebate program to range from $150,000 to $500,000 per year, conservatively adding up to over $400 million each year in purely administrative costs.

29. To date, I am not aware of any steps that any Defendant has taken to meaningfully respond to the issues raised in the AHA's comments or any other comment.

**Defendants' Have Not Appropriately Prepared for Implementation**

30. In addition to all of the substantive issues with Defendants' proposed rebate program, I understand from our members that they still have not received information they need to effectively implement this program at their hospitals.

31. HRSA has created a list of FAQs on its website and occasionally updated it since the comment period,[10] but these FAQs still do not address key concerns the AHA's members have

[8] 90 Fed. Reg. 44197.
[9] The Am. Hosp. Ass'n, *AHA Letter to HRSA re: The 340B Rebate Model Pilot Program* (Sept. 30, 2025), https://www.aha.org/lettercomment/2025-09-30-aha-letter-hrsa-re-340b-rebate-model-pilot-program.
[10] *See* HRSA, "340B Rebate Model Pilot Program" (Nov. 2025), https://www.hrsa.gov/opa/340b-model-pilot-program.

about rebate program implementation. For example, in response to the question "What should I do if I do not receive a rebate within 10 days of submitting claims data?," HRSA advises:

> Covered entities who are not receiving rebates within the 10-day timeframe after submitting complete and accurate data, should first contact the manufacturer and IT platform vendor to report concerns. If after attempting to work with the manufacturer a covered entity cannot resolve the issue with the manufacturer, the covered entity should email 340BPricing@hrsa.gov with the details of its concern. A manufacturer that is consistently unable to timely resolve rebate reimbursement issues may have its participation in the pilot program revoked.

This information does not address, among other issues: 1) who, between the manufacturer and the IT platform, is ultimately responsible for resolving issues; 2) to what degree covered entities will be expected to "attempt[] to work with the manufacturer" before HRSA will intervene; or 3) what it means for a manufacturer to be "consistently unable to timely resolve rebate reimbursement issues." All of this information is critical to our members' ability to plan for implementation of Defendants' rebate program, and Defendants have given very little guidance about what recourse covered entities can expect when drug companies do not comply with the 10-day window for issuing rebates.

32. The AHA also is concerned that Defendants' rebate program will not be operationally prepared to handle our members' rebate claims starting on January 1. It is my understanding that Defendants or their third-party administrators have not yet even tested the Beacon software program on which their entire rebate program relies. If this software does not function as intended, safety-net providers will be without a mechanism to obtain 340B pricing for nine popular and costly drugs in just one month.

33. The AHA also is concerned about the terms and conditions that are associated with the Beacon software program. I have heard from numerous AHA members that they would not ordinarily agree to such one-sided conditions. Among other things, AHA members have raised

concerns about 1) allowing their claims data to be sold for profit, 2) cybersecurity and data privacy risks, and 3) strict limits on liability. I also have learned that members have tried to negotiate those conditions, but the creator of the Beacon software has refused to make any changes and Defendants have refused to step in.

**Defendants' Planned Rebate Program Will Cause Harm to the AHA's Members**

34. Despite the AHA and other commenters detailing the harm that Defendants' rebate program would cause, I am not aware that Defendants have taken any meaningful steps to change the rebate program to mitigate harm to hospitals and other safety-net healthcare providers.

35. Even temporary outlays of the large amounts of cash needed to purchase drugs at WAC can have dire consequences for our members. For example, it is common for hospitals that participate in the 340B program to use bond financing to raise money for new projects that enhance patient care. Those bonds typically include covenants that require the hospital to maintain a certain number of days of cash on hand. Forced expenditures for new drugs under Defendants' rebate program threaten to deplete some of our members' cash reserves beyond what is required by their bond covenants, and violating those covenants has severe consequences ranging from credit rating downgrades to increased costs of borrowing to closure.

36. With looming uncertainty about how much they will have to pay for drugs next year because of Defendants' rebate program, some of our members have also told the AHA that they have put off important new projects altogether—including delaying expansions of patient services, facilities improvements, and construction of new clinics to expand access to care.

37. Defendants' rebate program also jeopardizes the continuation of the many patient support programs that our members currently use their 340B savings for, including free or discounted medication programs, community health screenings and vaccine clinics, free or reduced

cost care for uninsured patients, and other healthcare support programs. With so many of our members operating on very thin or negative margins, they do not have excess funds to sustain their current service levels if forced to pay more for access to drugs.

38. Our member hospitals have been operating under the 340B discount model for over three decades and have built their pharmacy workflows and compliance practices around that model. The new requirements to submit additional deidentified patient-specific data to drug companies, track rebates that they are owed, and follow up with drug companies to make sure that rebates are actually paid will require additional resources that could otherwise be used for patient care. Our members have informed the AHA that they expect to need, on average, two additional full-time employees to comply with Defendants' rebate program, who will have to be hired anew with diverted funds or taken away from other tasks in service of the hospital's mission.

39. Between additional staffing costs, software expenditures, and other operational burdens, the AHA conservatively estimates that Defendants' planned rebate program will cost our members more than $400 million annually in administrative costs alone. Defendants have done nothing to clarify whether these additional administrative costs will be compensated by drug companies and, if so, how.

40. The AHA and other commenters, including some of our members themselves, brought imminent harms to Defendants' attention. But Defendants have chosen not to address them, instead moving ahead toward a January 1 implementation date for their rebate program. Our members have already started to incur non-recoverable costs in attempting to prepare for Defendants' rebate program, and the impact of these costs on patient care across the country will only worsen if Defendants' rebate program is not at least put on hold.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed this 26th day of November, 2025 at Washington, D.C.

*/s/ Chad Golder*

Chad Golder

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

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| THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,<br><br>Plaintiffs,<br><br>v.<br><br>ROBERT F. KENNEDY, JR. Secretary of the U.S. Department of Health and Human Services, ET AL.,<br><br>Defendants. | Case No.<br><br>**DECLARATION OF H. DAVID MANTZ IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER** |

I, H. David Mantz, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am the Chief Executive Officer ("CEO") of Dallas County Medical Center ("DCMC"), located in Fordyce, Arkansas. I assumed this role in 2022, and I have worked in the healthcare industry for over forty years. As CEO of DCMC, I am responsible for strategy, operations, and finances. I submit this declaration in support of Plaintiffs' motion for a temporary restraining order. The facts in this declaration are based on my personal knowledge and experience and my review of DCMC's business records.

2. For the first seventeen years of my career, I worked as a respiratory therapist. In 2003, I moved into healthcare administration, holding leadership positions across numerous organizations. Before joining DCMC as CEO, I worked as Chief Operating Officer of Mainline Health Systems from 2020 to 2021 and CEO of Chicot Memorial Medical Center for the eight years prior.

3. I earned a Bachelor's Degree in Healthcare Management from Ottawa University and a Master's Degree in Business Administration from Columbia Southern University.

**DCMC Provides Vital Services to a Vulnerable Population**

4. DCMC opened to the public on May 4, 1958. We currently operate a twenty-five bed Critical Access Hospital in Fordyce, Arkansas. With a population of just under 3,400 people, Fordyce is the seat of Dallas County. DCMC commonly treats patients from the towns of Princeton, Tulip, Dalark, Sparkman, Carthage, and Farindale. DCMC is the largest employer in the county, which is known for its timber, farming, and railroad industries.

5. DCMC serves an elderly and low-income, rural population. Dallas County has been designated as a medically underserved area by the Defendant Health Resources and Services Administration.[1] The median income in Fordyce is nearly thirty percent below the Arkansas state average. Just eight percent of Fordyce residents have a bachelor's degree or higher, more than fifty percent of the residents are unemployed, and over thirty percent receive disability benefits.[2] To educate the community about DCMC's offerings, DCMC staff go to festivals and other events and engage with community members.

6. DCMC is proud to serve our community, including the underinsured and uninsured patients who cannot afford to pay for their medical services. DCMC operates a Level 4 Trauma Center and a 24-hour emergency room. We are Stroke-Certified and have received recognition for our wound care services. DCMC also offers infusion services, radiology services, outpatient therapy, laboratory services, and operates two rural primary care clinics. DCMC policy is to

[1] Health Res. & Servs. Admin., *MUA Find*, https://data.hrsa.gov/tools/shortage-area/mua-find (last visited Nov. 23, 2025).

[2] U.S. Census Bureau, *Fordyce, AR*, https://data.census.gov/profile/Fordyce_city,_Arkansas?g=160XX00US0524220 (last visited Nov. 23, 2025).

provide health care services regardless of a patient's ability to pay. DCMC maintains a dedicated financial assistance program for eligible patients.

7. Despite DCMC's best efforts, access to care remains a substantial challenge in Dallas County. For example, there is no mental health counseling available in the entire county, and the closest oncologist is an hour drive each way. Our patients also face barriers to maintaining their health with the closest grocery store being thirty miles away.

8. Given the vital—and irreplaceable—services we offer, DCMC has been designated by Defendant Department of Health and Human Services as an "Essential Community Provider" that serves "primarily low-income and medically underserved populations."[3]

**DCMC Cannot Afford to Pay the Retail Costs of Drugs**

9. DCMC is in a delicate financial position. We have extremely limited cash on hand, and our operating margin has decreased each of the past three years. In 2023, we achieved a margin of $380,000, but year-to-date, our margin is only $180,000. We hope to break even in 2025. Post-pandemic staffing shortages, increased supply costs, and diminished reimbursement from insurers, including Medicaid and Medicare Advantage, drive these decreasing margins.

10. As a county entity, DCMC's goal is not to make a profit, but DCMC must maintain operating capital to stay open and prevent patients from losing access to care. DCMC does not have excess funds to pay exorbitant prices for prescription drugs and wait to be reimbursed.

**Defendants' Planned Rebate Program Will Harm DCMC and Our Patients**

11. DCMC has participated in the 340B Program since 2010. We save approximately $1.1 million annually through the Program.

[3] *HHS Rolling Draft Essential Community Provider (ECP) List for the Federally-facilitated Marketplace*, Ctrs. for Medicare & Medicaid Servs., https://data.healthcare.gov/rolling-draft-list (last visited Nov. 23, 2025).

12. Our 340B savings are incorporated into our operating budget and have enabled us to expand service lines in recent years. For example, we constructed a telehealth clinic for oncology patients, created an intensive outpatient psychiatric program for seniors, and opened multiple primary care outpatient clinics. We have also implemented a new electronic medical record to facilitate efficiency and other improvements, and we've been developing a new infusion program. These service lines and clinics are critical for our patients. Prior to the telehealth oncology clinic, cancer patients in Dallas County would be forced to take a two-hour roundtrip to see their physician.

13. As mentioned previously, we treat patients regardless of their ability to pay. The 340B Program allows us to administer our financial assistance program for those patients.

14. In addition, the 340B Program has allowed DCMC to complete critical maintenance and recruit and retain staff. For example, the roof on our nearly seventy-year-old building was in such disrepair this past summer that DCMC staff had to place buckets and cookware around the hospital to catch leaks when it rained. Using savings from the 340B Program, we were able to replace the roof without taking on debt. We also used 340B savings to complete a substantial maintenance project on our outpatient therapy building in 2025. 340B savings additionally permit us to pay our nurses a state-average salary, despite Dallas County's rural, low-income designation. Without the 340B Program, it would be impossible to maintain our facility, equipment, and staffing levels.

15. DCMC still has several essential projects that require completion, and I am sure that more will arise as we continue to operate the Medical Center. For example, our boiler room needs at least at least $35,000 in maintenance, and our outpatient therapy building needs an $8,000 ramp for disabled patients. The hospital lacks a wheelchair-accessible shower, which we have been

planning to build. DCMC had also planned to repurpose an old nursing home for an employee daycare, a vital tool to recruit working mothers and decrease labor costs. Children in Dallas County also suffer from a severe lack of access to care, so DCMC had planned a telehealth clinic in a local school. Defendants' Rebate Program forced us to curb or halt all these projects.

16. DCMC administers at least one of the drugs selected for Defendants' rebate program. Fronting the wholesale acquisition costs of drugs—even briefly—will cause significant operational issues for us, given our limited cash on hand. DCMC does not have the liquidity to float its operating capital to drug companies for unknown periods of time and without the guarantee of rebates.

17. We are also concerned about the Rebate Program because drug companies have little incentive to pay rebates, and Defendants have not established a meaningful dispute resolution process or enforcement mechanism. For example, Defendants did not set specific penalties for drug companies paying untimely rebates or even improperly denying rebates. And DCMC lacks the resources to meaningfully participate in a dispute resolution process that requires us to contest delayed and denied rebates against sophisticated drug companies.

18. We also do not have the staff to track and chase rebates and monitor the impact on our operational budget. DCMC administers the current 340B Program with a single internal employee. But we estimate that Defendants' rebate program will require thirty to sixty hours of staff time each week. Therefore, we will have to hire two additional full-time employees, one in the pharmacy department and another in accounting, but we do not believe it is realistic to hire and train these employees by January 1, 2026. We also anticipate an increase in vendor fees. The addition of two employees to handle purely administrative tasks, coupled with an increase in vendor fees, will materially impact our margins and ability to serve patients.

19. DCMC also is concerned that it must submit data to Beacon, the private, third-party platform chosen by drug manufacturers. Beacon sent its unreasonable terms and conditions on a take-it-or-leave-it basis, meaning we had no choice but to accept those terms to gain access to the 340B price of the drugs included in Defendants' rebate program. We do not know how Beacon will secure our patients' data, which is an issue we take very seriously. And Beacon causes us great concern because it has given itself the right to retain this patient data, even if the rebate program is discontinued, and can sell this patient data to other third parties. Compounding all of our concerns is the fact that Beacon can amend the terms at any time and that Beacon requires us to broadly waive our liability rights against Beacon. DCMC would not ordinarily agree to terms like these if we were not forced to do so.

20. Due to the increased administrative costs of Defendants' rebate program and the uncertainty of whether and when we will receive rebates, we have paused maintenance projects, service line expansions, and equipment replacements. Defendants' rebate program has already forced us to delay critical maintenance, including to our boiler room and outpatient therapy building. The rebate program has also prevented us from installing handicap-accessible showers in the hospital, building a daycare for employees, and implementing a telehealth clinic for underserved children. We fear the increased costs from Defendants' rebate program will force us to cut unprofitable service lines, such as our telehealth oncology clinic. Ultimately, the financial pressure from the rebate program could force DCMC to leave the 340B Program altogether.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed this 26th day of November, 2025 at Germantown, Tennessee.

*/s/ H. David Mantz*

H. David Mantz

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

| | |
|---|---|
| THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, DALLAS COUNTY MEDICAL CENTER,<br><br>Plaintiffs,<br><br>v.<br><br>ROBERT F. KENNEDY, JR. Secretary of the U.S. Department of Health and Human Services, ET AL.,<br><br>Defendants. | Case No.<br><br>**DECLARATION OF ALAN W. O'NEIL IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER** |

I, Alan W. O'Neil, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am the CEO of Unity Medical Center ("Unity") in Grafton, North Dakota. I have been the CEO at Unity for more than eleven years and am ultimately responsible for Unity's operations and finances. I submit this declaration in support of Plaintiffs' motion for a temporary restraining order. The facts in this declaration are based on my personal knowledge and experience, and my review of Unity's business records.

2. I have worked in healthcare administration for over forty years. I began my career in 1983 at Lutheran Health Systems (now Banner Health) in Fargo, North Dakota in information technology and advanced through numerous leadership positions. From 1986 through 1998, I was the Director of Fiscal Services at Fairbanks Memorial Hospital in Fairbanks, Alaska. From 1998 through 2007, I was the Director of Operations – Department of Family Medicine at the University of North Dakota School of Medicine and Health Sciences. From 2007 through 2012, I was the Chief Financial Officer at Jamestown Regional Medical Center in Jamestown, North Dakota. For

the next two years, I was the Executive Vice President of the East Region at Health Management Services, based out of Billings, Montana. In 2014, I became the CEO at Unity and have served in that position ever since.

3. I earned an undergraduate degree in Business Administration from Mayville State University and hold an MBA from the University of Mary. I just concluded my full term as a member of the Region 6 Policy Board for the American Hospital Association and have served on the North Dakota Hospital Association Board for nine years, including in the Chair position. I won the AHA Grassroots Award in 2021. I also received the 2025 Outstanding Rural Health Career Award, which recognizes a healthcare professional who has devoted his or her career to making significant contributions to improving healthcare in rural North Dakota. I just received (on November 20, 2025) the State of ND "Star" award from the Center for Rural Health in conjunction with National Rural Health Day.

4. I am familiar with Defendants' plan to replace the 340B program's current discount model with a rebate program starting on January 1, 2026, for nine popular drugs. I also know the harm that this rebate program will cause Unity if it goes into effect next month.

**Unity Provides Critical Care to an Underserved Population**

5. For more than 110 years, a Grafton, North Dakota-based hospital has served Walsh County and the surrounding region. Today, we provide access to healthcare for 10,000 patients. We operate a fourteen-bed Critical Access Hospital and two primary care clinics.

6. Our patient population is largely elderly and rural; more than twenty percent of Grafton citizens are aged sixty-five or older. Walsh County has been designated by Defendant Health Resources and Services Administration as a medically underserved area.[1] Data from the

[1] Health Res. & Servs. Admin., *MUA Find*, https://data.hrsa.gov/tools/shortage-area/mua-find (last visited Nov. 23, 2025).

2020 census shows that the median income in Grafton is twenty-three percent below the median income in the state of North Dakota, and just eighteen percent of Grafton residents hold a bachelor's degree or higher.[2] Grafton's rate of employment is sixty-three percent, and seventeen percent of our citizens receive disability benefits. The primary industries in the area are agriculture and manufacturing.

7. Unity offers a range of critical service lines, including: inpatient and swing-bed care, an emergency department, oncology, same-day surgery, cardiac and pulmonary rehabilitation, chronic disease treatment, an infusion center, mental health counseling, radiology, laboratory, respiratory care, and physical, occupational and speech therapy. We have won numerous awards, such as being named a top 100 Critical Access Hospital. Unity also provides education for medical students interested in serving a rural population in conjunction with the University of North Dakota Medical School.

8. Approximately fifty percent of our patient visit revenue comes from Medicare beneficiaries. Access to transportation for medical care and prescriptions is a serious challenge in our area, which we have attempted to address by purchasing a van to transport patients.

**Unity Cannot Bear the Increased Costs of Defendants' Rebate Program**

9. Unity does not have the resources to pay exorbitant upfront costs for medications and wait for drug companies to reimburse us. Year-to-date, our operating margin is less than 3%, and we have a very limited amount of cash on hand.

10. As a 501(c)(3) non-profit healthcare system, our goal is the same as that of the 340B Program: to stretch our resources as far as possible to provide care to our community.

[2] U.S. Census Bureau, *Grafton, ND*, https://data.census.gov/profile/Grafton_city,_North_Dakota?g=160XX00US3831820.

**The Rebate Program Will Harm Unity and Its Patients**

11. Unity has participated in the 340B Program since 2016. We save approximately $550,000 annually through the Program.

12. We incorporate our 340B savings into our overall operating budget, which has allowed us to expand service lines and improve our facilities. In 2019, we broke ground on a thirty-six thousand square foot, three-story addition to modernize our 1958 hospital. This addition was opened in 2021. The savings from the 340B program were incorporated into the Financial Feasibility Study as we applied for loans through the USDA and the Bank of North Dakota. These savings were an integral part of our financial ratios that allowed us to be approved for the financing for this project. We are still servicing nearly twenty million dollars of principal balance on these outstanding loans. Also, we have added cardiac and pulmonary rehabilitation services, hiring employees to staff those service lines. With the new addition, we have built surgical suites, hired surgeons, and acquired surgical equipment we otherwise would not have been able to afford without 340B savings. We built a pharmacy and hired pharmaceutical staff. We also renovated our 1990 clinic using 340B savings, and we bought a van and hired a driver to improve patient access to care. Losing any of these services would leave a significant healthcare void in our community.

13. We also planned additional projects to enhance care quality and access, both of which would rely on 340B savings. For example, our current pharmacy (part of the 1958 original hospital) is in serious need of modernization and expansion. We have been designing that expansion, and, in fact, we just had a local fundraiser for that project on November 14, 2025. We also have been making plans to expand our chemotherapy services. Defendants' 340B rebate program has caused us to re-think both; as a result of that program, we may not have the available funds to proceed with these important projects.

14. The 340B Program also allows us to administer a financial assistance program for eligible patients.

15. Unity administers all nine drugs included in Defendants' Rebate Program scheduled to start on January 1, 2026: Eliquis, Enbrel, Farxiga, Imbruvica, Januvia, Jardiance, Novolog, Stelara, and Xarelto.

16. Fronting the wholesale acquisition cost for these drugs will cause significant cash constraints for Unity. As a rural, non-profit hospital, we do not have the resources to float our operating capital to drug companies in order to access the 340B price of these drugs.

17. Because Defendants have not detailed the consequences drug companies will face if they do not timely pay rebates, or if they inappropriately deny rebates, Unity has great concern Defendants' rebate program will put our liquidity at risk. For example, drug companies will not be required to pay penalties if they do not issue rebates within ten days, or if they improperly deny rebates. Without a specific enforcement mechanism, I fear drug companies will not pay rebates timely, or they will refuse to pay them altogether. Further, Defendants' dispute resolution process will require us to challenge rebate denials with the drug companies themselves. Unity does not have the resources to take on the pharmaceutical industry over every contested rebate.

18. Unity will also have to dedicate significant staffing resources to Defendants' rebate program. We estimate that our administrative costs to track the status of the claims, rebates, and denials will be $100,000 in the first year. This administrative cost for a so-called "pilot program" is 20% of our *entire* discount from the 340B Program. We also do not think we can be prepared to implement the program internally by January 1, 2026.

19. Beacon, the drug companies' chosen, private, third-party platform, also causes us great concern. Beacon sent us unreasonable terms on a take-it-or-leave-it basis. While we

ordinarily would not accept such terms, Beacon is the only way to access the 340B price of the drugs included in the rebate program, which puts us in an impossible position. It is also unclear to us what kinds of precautions Beacon will take with our patients' information, which is a top priority for us. Moreover, Beacon gave itself the unilateral right to sell our patients' data, even after the rebate program has ended, and Beacon can amend its terms at any time. Beacon also requires us to waive nearly all rights we might have to a claim against it. Again, we would not usually accept such one-sided terms, but Defendants' rebate program has left us no choice.

20. Because of the uncertainty of Defendants' rebate program, Unity has paused facility improvement projects and service line expansions. For example, our pharmacy expansion has been put on hold and so have our expanded chemotherapy services. If the administrative costs and burden of Defendants' rebate program are too great, Unity simply will not be able to order the drugs included in the rebate program through the 340B process, which will eliminate a key source of liquidity and drive down our margins. Thus, Defendants' rebate program threatens to undermine the express purpose of the 340B Program itself, which is to allow us to stretch our resources and serve an underserved population in a very remote area of North Dakota.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed this 26th day of November, 2025 at Grafton, North Dakota.

*/s/ Alan W. O'Neil*

Alan W. O'Neil

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

| | |
|---|---|
| THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,<br><br>Plaintiffs,<br><br>v.<br><br>ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, ET AL.<br><br>Defendants. | Case No.<br><br>**DECLARATION OF L. RUSH ATKINSON IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER** |

I, L. Rush Atkinson, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am a partner at Dunn Isaacson Rhee LLP, counsel for Plaintiffs American Hospital Association ("AHA"), Maine Hospital Association, St. Mary's Regional Medical Center, Nathan Littauer Hospital & Nursing Home, Unity Medical Center, and Dallas County Medical Center in the above-captioned matter. I am a member in good standing of the State Bars of New York and the District of Columbia. I submit this declaration to attach exhibits supportive of Plaintiffs' Motion for a Temporary Restraining Order, all of which are publicly available.

2. Attached hereto as **Exhibit 1** is a true and correct copy of a letter from Chantelle V. Britton (Health Resources & Services Administration ("HRSA")) to Perry Elizabeth Knight (Johnson & Johnson), dated August 14, 2024 and its transmittal email, bates stamped 340B_REBATES_000064 and filed in *Eli Lilly & Co. v. Kennedy*, No. 1:24-cv-03220 (D.D.C. 2024) (the "*Eli Lilly* Case"), Dkt. 60-1.

3. Attached hereto as **Exhibit 2** is a true and correct copy of a letter from Chantelle V. Britton (HRSA) to Joaquin Duato (Johnson & Johnson), dated September 17, 2024 and its transmittal email, bates stamped 340B_REBATES_000201 and filed in the *Eli Lilly* Case, Dkt. 60-1.

4. Attached hereto as **Exhibit 3** is a true and correct copy of a letter from Carole Johnson (HRSA) to Joaquin Duato (Johnson & Johnson), dated September 27, 2024 and its transmittal email, bates stamped 340B_REBATES_000212 and filed in the *Eli Lilly* Case, Dkt. 60-1.

5. Attached hereto as **Exhibit 4** is a true and correct copy of a letter from Chantelle V. Britton (HRSA) to Lucas Montarce (Eli Lilly and Company), dated September 18, 2024, bates stamped 340B_REBATES_000292 and filed in the *Eli Lilly* Case, Dkt. 60-1.

6. Attached hereto as **Exhibit 5** is a true and correct copy of a letter from Chantelle V. Britton (HRSA) to Linda Kamin (Bristol Myers Squibb), dated November 4, 2024, bates stamped 340B_REBATES_000342 and filed in the *Eli Lilly* Case, Dkt. 60-1.

7. Attached hereto as **Exhibit 6** is a true and correct copy of a letter from Chantelle V. Britton (HRSA) to Scott Bray (Sanofi-Aventis US LLC), dated November 12, 2024, bates stamped 340B_REBATES_000380 and filed in the *Eli Lilly* Case, Dkt. 67-4.

8. Attached hereto as **Exhibit 7** is a true and correct copy of a letter from Chantelle V. Britton (HRSA) to Odalys Caprisecca (Novartis Pharmaceuticals Corp), dated January 14, 2025, bates stamped 340B_REBATES_000439 and filed in the *Eli Lilly* Case, Dkt. 60-1.

9. Attached hereto as **Exhibit 8** is a true and correct copy of a comment submitted by the American Hospital Association on the 340B Program Notice (Federal Register No. 2025-

14998) on August 27, 2025, comment ID HRSA-2025-0001-0052, available at https://www.regulations.gov/comment/HRSA-2025-0001-0052.

10. Attached hereto as **Exhibit 9** is a true and correct copy of a comment submitted by The Craneware Group on the 340B Program Notice (Federal Register No. 2025-14998) on August 28, 2025, comment ID HRSA-2025-0001-0076, available at https://www.regulations.gov/comment/HRSA-2025-0001-0076.

11. Attached hereto as **Exhibit 10** is a true and correct copy of a comment submitted by UVA Health on the 340B Program Notice (Federal Register No. 2025-14998) on September 5, 2025, comment ID HRSA-2025-0001-0110, available at https://www.regulations.gov/comment/HRSA-2025-0001-0110.

12. Attached hereto as **Exhibit 11** is a true and correct copy of a comment submitted by Sanford Health on the 340B Program Notice (Federal Register No. 2025-14998) on September 5, 2025, comment ID HRSA-2025-0001-0378, available at https://www.regulations.gov/comment/HRSA-2025-0001-0378.

13. Attached hereto as **Exhibit 12** is a true and correct copy of a comment submitted by UNC Health on the 340B Program Notice (Federal Register No. 2025-14998) on September 5, 2025, comment ID HRSA-2025-0001-0401, available at https://www.regulations.gov/comment/HRSA-2025-0001-0401.

14. Attached hereto as **Exhibit 13** is a true and correct copy of a comment submitted by Norton Healthcare on the 340B Program Notice (Federal Register No. 2025-14998) on September 8, 2025, comment ID HRSA-2025-0001-0621, available at https://www.regulations.gov/comment/HRSA-2025-0001-0621.

15. Attached hereto as **Exhibit 14** is a true and correct copy of a comment submitted by Speare Memorial Hospital on the 340B Program Notice (Federal Register No. 2025-14998) on September 8, 2025, comment ID HRSA-2025-0001-0802, available at https://www.regulations.gov/comment/HRSA-2025-0001-0802.

16. Attached hereto as **Exhibit 15** is a true and correct copy of a comment submitted by University Health on the 340B Program Notice (Federal Register No. 2025-14998) on September 8, 2025, comment ID HRSA-2025-0001-0870, available at https://www.regulations.gov/comment/HRSA-2025-0001-0870.

17. Attached hereto as **Exhibit 16** is a true and correct copy of a comment submitted by Hall, Render, Killian, Heath & Lyman, P.C. on the 340B Program Notice (Federal Register No. 2025-14998) on September 8, 2025, comment ID HRSA-2025-0001-0974, available at https://www.regulations.gov/comment/HRSA-2025-0001-0974.

18. Attached hereto as **Exhibit 17** is a true and correct copy of a comment submitted by The Hospital and Healthsystem Association of Pennsylvania on the 340B Program Notice (Federal Register No. 2025-14998) on September 8, 2025, comment ID HRSA-2025-0001-1074, available at https://www.regulations.gov/comment/HRSA-2025-0001-1074.

19. Attached hereto as **Exhibit 18** is a true and correct copy of a comment submitted by 340B Health on the 340B Program Notice (Federal Register No. 2025-14998) on September 8, 2025, comment ID HRSA-2025-0001-1111, available at https://www.regulations.gov/comment/HRSA-2025-0001-1111.

20. Attached hereto as **Exhibit 19** is a true and correct copy of a comment submitted by Lowell Community Health Center on the 340B Program Notice (Federal Register No. 2025-

14998) on September 3, 2025, comment ID HRSA-2025-0001-0106, available at https://www.regulations.gov/comment/HRSA-2025-0001-0106.

21. Attached hereto as **Exhibit 20** is a true and correct copy of a comment submitted by Erlanger Medical on the 340B Program Notice (Federal Register No. 2025-14998) on September 6, 2025, comment ID HRSA-2025-0001-0495, available at https://www.regulations.gov/comment/HRSA-2025-0001-0495.

22. Attached hereto as **Exhibit 21** is a true and correct copy of a comment submitted by Lindsborg Community Hospital on the 340B Program Notice (Federal Register No. 2025-14998) on September 2, 2025, comment ID HRSA-2025-0001-0099, available at https://www.regulations.gov/comment/HRSA-2025-0001-0099.

23. Attached hereto as **Exhibit 22** is a true and correct copy of a comment submitted by the American Hospital Association, America's Essential Hospitals, the American Society of Health-Systems Pharmacists, the Association of American Medical Colleges, the Catholic Health Association of the United States, the Children's Hospital Association, and 340B Health on the 340B Program Notice (Federal Register No. 2025-14998) on August 8, 2025, comment ID HRSA-2025-0001-0005, available at https://www.regulations.gov/comment/HRSA-2025-0001-0005.

24. Attached hereto as **Exhibit 23** is a true and correct copy of a comment submitted by MCR Health on the 340B Program Notice (Federal Register No. 2025-14998) on September 8, 2025, comment ID HRSA-2025-0001-0215, available at http://regulations.gov/comment/HRSA-2025-0001-0215.

25. Attached hereto as **Exhibit 24** is a true and correct copy of a comment submitted by Family HealthCare on the 340B Program Notice (Federal Register No. 2025-14998) on

September 8, 2025, comment ID HRSA-2025-0001-0842, available at https://www.regulations.gov/comment/HRSA-2025-0001-0842.

26. Attached hereto as **Exhibit 25** is a true and correct copy of a comment submitted by Corewell Health on the 340B Program Notice (Federal Register No. 2025-14998) on September 8, 2025, comment ID HRSA-2025-0001-0549, available at https://www.regulations.gov/comment/HRSA-2025-0001-0549.

27. Attached hereto as **Exhibit 26** is a true and correct copy of a comment submitted by CommonSpirit on the 340B Program Notice (Federal Register No. 2025-14998) on September 8, 2025, comment ID HRSA-2025-0001-0465, available at https://www.regulations.gov/comment/HRSA-2025-0001-0465.

28. Attached hereto as **Exhibit 27** is a true and correct copy of a comment submitted by the National Rural Health Association on the 340B Program Notice (Federal Register No. 2025-14998) on September 8, 2025, comment ID HRSA-2025-0001-0748, available at https://www.regulations.gov/comment/HRSA-2025-0001-0748.

29. Attached hereto as **Exhibit 28** is a true and correct copy of a comment submitted by Hudson Headwaters Health Network on the 340B Program Notice (Federal Register No. 2025-14998) on August 29, 2025, comment ID HRSA-2025-0001-0951, available at https://www.regulations.gov/comment/HRSA-2025-0001-0951.

30. Attached hereto as **Exhibit 29** is a true and correct copy of an Emergency Clearance Memo for the 340B Rebate Model Pilot Program submitted by Thomas J. Engels (Administrator, HRSA) to Jeffrey Clark (Acting Administrator of the Office of Information and Regulatory Affairs) on or about August 25, 2025, available at https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202508-0906-002.

31. Attached hereto as **Exhibit 30** is a true and correct copy of a supporting statement submitted by HRSA to the Office of Management and Budget on or about August 21, 2025, available at https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202508-0906-002.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed this 1st day of December, 2025 at Washington, D.C.

L. Rush Atkinson

# EXHIBIT 1

| | |
|---|---|
| **From:** | HRSA HSB 340B Pricing |
| **To:** | Knight, Perry [JJCUS] |
| **Cc:** | Britton, Chantelle (HRSA); Pedley, Krista (HRSA); Herzog, Michelle (HRSA); Burgess, William (HHS/OGC); Hargrove, Sherine (HHS/OGC); "JKiechel@ITS.JNJ.com"; Handwerker, Jeffrey L.; "Paula.Ramer@arnoldporter.com" |
| **Subject:** | RE: J&J Letter re: Rebate Model |
| **Date:** | Wednesday, August 14, 2024 3:50:21 PM |
| **Attachments:** | HRSA to JnJ regarding rebate model proposal 8.14.24.pdf<br>image001.png |

Dear Perry,

Please find the attached letter.

**Chantelle V. Britton, M.P.A., M.S. (she/her)**
Director
Office of Pharmacy Affairs
Office of Special Health Initiatives

HRSA
Health Resources & Services Administration

Sign up for email updates!

**From:** Knight, Perry [JJCUS] <PKnight@ITS.JNJ.com>
**Sent:** Wednesday, July 31, 2024 10:37 PM
**To:** Pedley, Krista (HRSA) <KPedley@hrsa.gov>; Britton, Chantelle (HRSA) <CBritton@hrsa.gov>; Burgess, William (HHS/OGC) <William.Burgess@hhs.gov>; Hargrove, Sherine (HHS/OGC) <Sherine.Hargrove@hhs.gov>
**Cc:** Kiechel, Julia [JJCUS] <JKiechel@ITS.JNJ.com>; Jeffrey.Handwerker <Jeffrey.Handwerker@arnoldporter.com>; Ramer, Paula <Paula.Ramer@arnoldporter.com>
**Subject:** [EXTERNAL] J&J Letter re: Rebate Model

Rear Admiral Pedley, Director Britton, Mr. Burgess, and Ms. Hargrove – thank you again for meeting with us last week. Attached please find the letter that you requested during our meeting regarding legal support for the rebate model. Please do not hesitate to let us know if you have any questions. We appreciate your attention to this matter and commitment to the 340B program.

Regards,
Perry

**Perry Elizabeth Knight**
Vice President, Law - Strategic Customer Group

**Johnson & Johnson**
Law Department

Johnson & Johnson
1125 Trenton Harbourton Road
Titusville, NJ 08560
+1 703 989-2654

pknight@its.jnj.com

HRSA
Health Resources & Services Administration
**Office of Special Health Initiatives**
5600 Fishers Lane
Rockville, MD 20857

August 14, 2024

**BY EMAIL**
Perry Elizabeth Knight
Vice President, Law – Strategic Customer Group
Johnson & Johnson

Dear Perry Knight:

The Health Resources and Services Administration (HRSA) has reviewed the information submitted in your July 31, 2024, correspondence, regarding Johnson & Johnson's (J&J) proposal to implement a 340B rebate model. You indicated that J&J intends to implement its proposed rebate model on October 15, 2024. The 340B statute states that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, *as provided by the Secretary*) to the manufacturer" shall not exceed the statutory ceiling price formula. 42 U.S.C. § 256b(a)(1) (emphasis added). To date, the Secretary has not provided for such rebate as proposed by J&J. Therefore, implementing such a proposal at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval of a rebate model such as J&J has proposed.

In addition, HRSA requests responses to the following questions:

1. J&J states that although J&J currently employs a chargeback model for 340B sales, J&J intends to shift to the rebate model. This shift would disrupt how the 340B Program has operated for over thirty years. As a result of this shift, covered entities, including those which primarily serve rural and underserved populations, would need to pay significantly higher prices on prescription drugs at the time of purchase.
    a. Has J&J conducted an evaluation of the impact of this proposal on the scope and breadth of health care access for patients served by affected covered entities?
    b. Has J&J conducted an analysis of the extent of the additional burden and/or costs to the affected covered entities, particularly those that are the sole or primary source of health care in a rural or underserved community?

2. J&J states that it will require covered entities to submit rebate claims to the rebate platform within 45 days of the date of the dispense.
    a. What specific claims level information would covered entities be required to submit?
    b. What other parties, if any, would J&J share the claims data with?

c. What protections and safeguards would J&J plan to implement to ensure such information would solely be used in support of the 340B Program?
d. What protections and safeguards would J&J plan to implement to ensure the privacy and security of such information?

3. J&J states that "[a] key feature of the Rebate Model is that it will ensure timely access to claims-level data, greatly reducing the risk of J&J being required to pay duplicate discounts both within the 340B program and across other government and commercial channels." Yet the 340B statute prohibits duplicate discounts only with respect to the Medicaid program.
    a. What authority does J&J believe it has to impose such a proposal with respect to other government programs or channels?
    b. What other government and commercial channels would this include?
    c. Which specific categories of providers, in addition to those that participate in the 340B Program, would J&J also require to use this model?

4. If J&J identifies a potential 340B duplicate discount, how will the rebate claim be adjudicated?
    a. What is the timeframe that J&J will process any such adjudication?
    b. What reconsideration or appeals process will J&J implement?
    c. Will J&J automatically deny covered entities' 340B rebate claims if J&J believes a Medicaid rebate was already paid?
    d. Will J&J automatically deny Medicaid rebate claims if J&J believes a covered entity's 340B rebate claims have already been paid?

5. What are the specific reasons that will lead J&J to reject claims?
    a. Will J&J make these reasons publicly available in advance of adjudication of claims?
    b. Will covered entities receive claim-by-claim information from J&J regarding which claims were rejected and on what basis?
    c. What reconsideration or appeals process will J&J implement to ensure covered entities receive any 340B discounts that are due as required by statute?

6. Your letter references a series of "checks" as part of a "validation process," please detail what these "checks" and "process" would entail, including how they align with the compliance requirements in the 340B statute?

7. With respect to the use of pharmacies with which covered entities contract:
    a. Will covered entities need to demonstrate that they purchased individual drugs subject to the rebate claim at wholesale acquisition cost?

b. Will this process require covered entities to maintain a separate stock of drugs at the contract pharmacy?
c. If so, how does J&J plan to ensure this process does not functionally deny covered entities access to the 340B price required by the statute given the additional upfront cost and administrative burden for covered entities, particularly low-margin safety net providers?

8. Would the rebate be paid at the package level or at the dispense level?
    a. Would rebates be paid to covered entities as soon as there is a full package or will covered entities receive a rebate based on the quantity dispensed per claim?
    b. How would J&J engage with covered entities with respect to these specifics of their prescription drug acquisition and distribution practices?

9. In 2023, J&J requested that HRSA post four different refund notices to covered entities on its website as part of standard restatements of 340B drugs. As part of that process, J&J issued refund adjustments through wholesalers. Under this model, how will J&J operationalize refunds when there are standard restatements in a way that supports the requirement to provide the 340B price?

10. Under this proposal, how would J&J treat current unreplenished accumulations?

11. Under J&J's plan, covered entities would be required to submit claims data to both 340B ESP and the rebate platform, yet HRSA has received a number of reports of technical and customer service difficulties with 340B ESP. How would J&J ensure covered entities could submit claims without technical difficulties or delays and would be able to access customer support with any issues?

Please send your responses to 340BPricing@hrsa.gov.

Sincerely,

Chantelle V. Britton, M.P.A., M.S.
Director, Office of Pharmacy Affairs

# EXHIBIT 2

| | |
|---|---|
| **From:** | HRSA HSB 340B Pricing |
| **To:** | jduato@jnj.com |
| **Cc:** | ltrieu@its.jnj.com; Knight, Perry [JJCUS]; KNelson8@its.jnj.com; Britton, Chantelle (HRSA) |
| **Subject:** | Please review: 340B Program letter to Johnson & Johnson |
| **Date:** | Tuesday, September 17, 2024 9:45:03 AM |
| **Attachments:** | image001.png<br>HRSA to JJ Letter 09172024 - Final.pdf |

Please review the attached letter.

Thank you.

**Chantelle V. Britton, M.P.A., M.S. (she/her)**
Director
Office of Pharmacy Affairs
Office of Special Health Initiatives

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5600 Fishers Lane
Rockville, MD 20857

September 17, 2024

**BY EMAIL**

Joaquin Duato
Chairman and Chief Executive Officer
Johnson & Johnson

Dear Joaquin Duato:

The Health Resources and Services Administration (HRSA) understands that Johnson & Johnson (J&J) has publicly announced plans to implement a rebate model for sales of certain 340B covered outpatient drugs to particular covered entities as of October 15, 2024. By way of this correspondence, HRSA provides warning that this unapproved rebate proposal violates J&J's obligations under the 340B statute, and HRSA expects J&J to cease implementation of it.

Specifically, in a "Notice to 340B End Customers Regarding Purchases of STELARA and XARELTO," dated August 23, 2024, J&J stated that as of October 15, 2024, disproportionate share hospitals will be required to "purchase STELARA or XARELTO through wholesalers at a commercial price, such as the wholesale acquisition cost (WAC)" and afterwards, J&J may make a "rebate payment" that "equal[s] the difference between (i) WAC and (ii) the 340B ceiling price."

As HRSA noted in its August 14, 2024, letter to J&J, the 340B statute states that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, *as provided by the Secretary*) to the manufacturer" shall not exceed the statutory ceiling price. 42 U.S.C. § 256b(a)(1) (emphasis added).[1] The statute also provides that the ceiling price "represents the maximum price that covered entities may permissibly be required to pay for the drug," and that said agreement "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.*

[1] The agreement referenced in the statute—your Pharmaceutical Pricing Agreement (PPA) and PPA addendum—"are uniform agreements that recite the responsibilities § 340B imposes, respectively, on drug manufacturers and the Secretary of HHS." *Astra USA v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011). Contrary to J&J's assertions in its correspondence to HRSA, the Supreme Court has made clear that the PPAs reflect the obligations that the statute places on manufacturers who participate in the 340B Program; PPAs "are not transactional, bargained-for contracts" and are simply the manner drug manufacturers "opt into the 340B Program." *Id.*

The Secretary has not "provided" that the rebates described in J&J's notice should be "tak[en] into account" in the "amount required to be paid" for Stelara and Xarelto by disproportionate share hospitals. If J&J implements its rebate proposal without Secretarial approval, it will violate Section 340B(a)(1) of the Public Health Service (PHS) Act.

According to its Notice, J&J intends to unilaterally charge disproportionate share hospitals "commercial price[s], such as [WAC]" for covered outpatient drugs, starting October 15, 2024. In other words, J&J's rebate proposal would require disproportionate share hospitals to purchase Stelara and Xarelto at prices that exceed "the maximum price[s] that covered entities may permissibly be required to pay" for those drugs. This, too, violates Section 340B(a)(1) of the PHS Act.[2]

In correspondence with HRSA, J&J asserts that their proposed rebate model is similar to "replenishment" processes and that this authorizes J&J to unilaterally impose its proposed rebate model without violating the 340B statute. This is incorrect. There are fundamental differences between J&J's proposal and some covered entities voluntarily using inventory replenishment processes to manage their 340B inventory. First, under a typical replenishment structure, a covered entity generally makes an initial purchase at a higher price, then subsequent, ongoing drug purchases are at the 340B price. By contrast, under the J&J proposal, covered entities would be forced to pay a higher price point up front for *every* purchase. This would create significantly higher up-front costs for covered entities. Second, the 340B statute explicitly limits rebate models to those that have been approved by the Secretary. Third, covered entities voluntarily choose to use replenishment processes; J&J's proposal is not voluntary for covered entities.

Because J&J's rebate proposal, if implemented, violates J&J's obligations under the 340B statute, it subjects J&J to potential consequences, such as termination of J&J's Pharmaceutical Pricing Agreement (PPA). *See Astra USA v. Santa Clara Cnty.*, 563 U.S. 110 (2011). As stated in the PPA, even apart from "a violation of the Agreement," the Secretary may "terminate the Agreement" for "other good cause." In addition, the 340B statute provides for "[t]he imposition of sanctions in the form of civil monetary penalties" on "any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1)." 42 U.S.C. § 256b(d)(1)(B)(vi).

[2] J&J's August 15, 2024, notice does not commit to an enforceable timeframe for issuing the "rebate payment." In addition, the notice states that the "rebate payment" is subject to J&J's unilaterally imposed requirements for the timely submission of "Rebate Claim Data" by a covered entity, as well as J&J's "validat[ion]" of said data. In short, the notice makes clear that issuance of the "rebate payment" is conditioned on J&J's prior approval at J&J's sole discretion.

HRSA expects J&J to cease implementation of its rebate proposal immediately and to inform HRSA no later than September 30, 2024, in order to provide adequate notice to covered entities.

Please provide this notification to Chantelle Britton, Director of HRSA's Office of Pharmacy Affairs at cbritton@hrsa.gov.

Sincerely,

Carole Johnson
Administrator

cc:
Lena Kane
Senior Director Government Contract and Compliance, Johnson & Johnson

Perry Knight
Vice President, Law, Strategic Customer Group, Johnson & Johnson

# EXHIBIT 3

| | |
|---|---|
| **From:** | Britton, Chantelle (HRSA) |
| **To:** | jduato@jnj.com |
| **Cc:** | ltrieu@its.jnj.com; Knight, Perry [JJCUS]; KNelson8@its.jnj.com; HRSA HSB 340B Pricing |
| **Subject:** | RE: Please review: 340B Program letter to Johnson & Johnson |
| **Date:** | Friday, September 27, 2024 11:05:14 AM |
| **Attachments:** | image001.png<br>HRSA to JJ Letter 09272024.pdf |

Please find the attached letter for your review.

Thank you.

**Chantelle V. Britton, M.P.A., M.S. (she/her)**
Director
Office of Pharmacy Affairs
Office of Special Health Initiatives
Desk: 301-443-4749
Cell: 301-300-2185

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**From:** HRSA HSB 340B Pricing <340BPricing@hrsa.gov>
**Sent:** Tuesday, September 17, 2024 9:45 AM
**To:** jduato@jnj.com
**Cc:** ltrieu@its.jnj.com; Knight, Perry [JJCUS] <PKnight@ITS.JNJ.com>; KNelson8@its.jnj.com; Britton, Chantelle (HRSA) <CBritton@hrsa.gov>
**Subject:** Please review: 340B Program letter to Johnson & Johnson

Please review the attached letter.

Thank you.

**Chantelle V. Britton, M.P.A., M.S. (she/her)**
Director
Office of Pharmacy Affairs
Office of Special Health Initiatives


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5600 Fishers Lane
Rockville, MD 20857

September 27, 2024

Joaquin Duato
Chairman and Chief Executive Officer
Johnson & Johnson
Via email

Dear Joaquin Duato:

I am writing in response to Johnson & Johnson's (J&J) September 19, 2024, letter regarding J&J's decision to proceed with implementation of an unapproved rebate proposal for sales of certain covered outpatient drugs to particular covered entities.

In letters sent on August 14, 2024, and September 17, 2024, the Health Resources and Services Administration (HRSA) made clear that the 340B statute requires Secretarial approval of any rebate mechanism. Despite communicating this point to J&J multiple times, J&J's communications to HRSA, including J&J's September 19, 2024, letter, have not requested Secretarial approval.

Accordingly, as outlined in HRSA's September 17, 2024, letter, if J&J proceeds with implementing its rebate proposal without Secretarial approval, it will violate section 340B(a)(1) of the Public Health Service Act. If J&J has not notified HRSA that it is ceasing implementation of its rebate proposal by September 30, 2024, HRSA will begin the process outlined in J&J's Pharmaceutical Pricing Agreement related to terminating the agreement. In addition, if J&J moves forward with implementation of its rebate proposal, HRSA will initiate a referral to the HHS Office of Inspector General pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi).

To forestall these actions, J&J should – per HRSA's September 17, 2024, letter – inform HRSA by no later than September 30, 2024, that it has ceased implementation of its rebate proposal. Your response should be sent to Chantelle Britton, Director of HRSA's Office of Pharmacy Affairs at cbritton@hrsa.gov.

Sincerely,

Carole Johnson

cc: Lena Kane, Senior Director Government Contract and Compliance, Johnson & Johnson
Perry Knight, Vice President, Law, Strategic Customer Group, Johnson & Johnson

# EXHIBIT 4

Health Resources & Services Administration
**Office of Special Health Initiatives**
5600 Fishers Lane
Rockville, MD 20857

September 18, 2024

**BY EMAIL**
Lucas Montarce
Executive Vice President and Chief Financial Officer
Eli Lilly and Company
montarce_lucas@lilly.com

Dear Lucas Montarce:

The Health Resources and Services Administration (HRSA) has reviewed the information provided in the September 9, 2024, letter from Eli Lilly and Company (Lilly) regarding Lilly's proposal to implement a 340B rebate model. Lilly indicated that it intends to implement its proposed rebate model on November 1, 2024. The 340B statute states that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, *as provided by the Secretary*) to the manufacturer" shall not exceed the statutory ceiling price formula. 42 U.S.C. § 256b(a)(1) (emphasis added). To date, the Secretary has not provided for such rebate as proposed by Lilly. Therefore, implementing such a proposal at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval of a rebate model such as Lilly has proposed.

In addition, HRSA requests responses to the following questions:

1. Shifting to the rebate model would disrupt how the 340B Program has operated for over thirty years. As a result of this shift, covered entities, including those which primarily serve rural and underserved populations, would need to pay significantly higher prices on prescription drugs at the time of purchase.
    a. Lilly asserts that the rebate model will have no impact on patients. Has Lilly conducted an evaluation of the impact of this proposal on the scope and breadth of health care access for patients served by affected covered entities?
    b. Has Lilly conducted an analysis of the extent of the additional burden and/or costs to the affected covered entities, particularly those that are the sole or primary source of health care in a rural or underserved community?
    c. Lilly indicated that in "some" cases covered entities will receive the cash rebate before paying the upfront cost for the drug itself. Does Lilly have any estimates or has it performed any analysis indicating the proportion of transactions for which this might occur?

2. Lilly states that it will require covered entities to submit rebate claims to the rebate platform.
    a. What other parties, if any, would Lilly share the claims data with?
    b. What protections and safeguards would Lilly plan to implement to ensure such information would be used in support of the 340B Program?
    c. What protections and safeguards would Lilly plan to implement to ensure the privacy and security of such information?
    d. If available, please provide a copy of the Privacy Policy &Terms of Service (or similarly titled agreements) that would govern Kalderos, covered entities, and any other parties in this process.

3. If Lilly identifies a potential 340B duplicate discount, how will the rebate claim be adjudicated?
    a. What is the timeframe that Lilly will process any such adjudication?
    b. What reconsideration or appeals process will Lilly implement?
    c. Will Lilly automatically deny covered entities' 340B rebate claims if Lilly believes a Medicaid rebate was already paid?
    d. Will Lilly automatically deny Medicaid rebate claims if Lilly believes a covered entity's 340B rebate claims have already been paid?

4. Will covered entities receive claim-by-claim information from Lilly regarding which claims were rejected and on what basis?

5. What reconsideration or appeals process will Lilly implement to ensure covered entities receive any 340B discounts that are required by statute?

6. Lilly provided a listing of the data elements that it will collect for the validation of claims. Please indicate how these data elements align with the compliance requirements in the 340B statute. The documentation submitted by Lilly refers to a "reasonability check" for claim submissions relative to the date of service. Please explain what will be involved in this "reasonability check."

7. With respect to the use of pharmacies with which covered entities contract:
    a. Will covered entities need to demonstrate that they purchased individual drugs subject to the rebate claim at wholesale acquisition cost?
    b. Will this process require covered entities to maintain a separate stock of drugs at the contract pharmacy?
    c. If so, how does Lilly plan to ensure this process does not functionally deny covered entities access to the 340B price required by the statute given the additional upfront cost and administrative burden for covered entities, particularly low-margin safety net providers?

8. In 2023, Lilly requested that HRSA post two different refund notices to covered entities on its website as part of standard restatements of 340B drugs. As part of that process, Lilly issued refunds using wholesaler chargeback data. Under this model, how will Lilly operationalize refunds when there are standard restatements in a way that supports the requirement to provide the 340B price?

9. Under this proposal, how would Lilly treat current unreplenished accumulations?

10. Under Lilly's plan, contract pharmacy restrictions would be managed by Kalderos and the 340B ESP model would no longer be used. What transition time will be provided to covered entities that need to designate contract pharmacies in a new system? HRSA has received a number of reports of technical and customer service difficulties with 340B ESP. How would Lilly ensure covered entities could submit claims without technical difficulties or delays and would be able to access customer support without any significant issues under the Kalderos model?

Please send your responses to 340BPricing@hrsa.gov.

Sincerely,

Chantelle V. Britton, M.P.A., M.S.
Director, Office of Pharmacy Affairs

Cc:
Derek Asay, Senior Vice President, Government Strategy and Federal Accounts

# EXHIBIT 5

HRSA
Health Resources & Services Administration
**Office of Special Health Initiatives**
5600 Fishers Lane
Rockville, MD 20857

November 4, 2024

**BY EMAIL**
Linda Kamin
Executive Director, Contract Operations and Government Reporting
Bristol Myers Squibb
Linda.kamin@bms.com

Dear Linda Kamin:

The Health Resources and Services Administration (HRSA) has received the information submitted in your October 24, 2024, correspondence, regarding Bristol Myers Squibb's (BMS) proposal to implement a 340B rebate model in the Spring of 2025 for all 340B covered entities' purchases of Eliquis. The 340B statute states that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, *as provided by the Secretary*) to the manufacturer" shall not exceed the statutory ceiling price formula. 42 U.S.C. § 256b(a)(1) (emphasis added). To date, the Secretary has not provided for such a rebate model. Therefore, implementing such a proposal at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval of a rebate model such as BMS has proposed.

In addition, HRSA requests responses to the following questions:

1. Shifting to a rebate model would disrupt how the 340B Program has operated for over thirty years. As a result of this shift, covered entities, including those which primarily serve rural and underserved populations, would need to pay significantly higher prices on prescription drugs at the time of purchase.
    a. Has BMS conducted an evaluation of the impact of this proposal on the scope and breadth of health care access for patients served by affected covered entities?
    b. Has BMS conducted an analysis of the extent of the additional burden and/or costs to the affected covered entities, particularly those that are the sole or primary source of health care in a rural or underserved community?

2. BMS states that it will require covered entities to submit rebate claims to the rebate platform.
    a. What, if any, timeframes must covered entities submit data from the date of dispense to qualify for a rebate under BMS' terms?
    b. What other parties, if any, would BMS share the claims data with?
    c. What protections and safeguards would BMS plan to implement to ensure such information would solely be used in support of the 340B Program?

d. What protections and safeguards would BMS plan to implement to ensure the privacy and security of such information?

3. BMS states that when a covered entity agrees to "share" the benefit of the 340B Price with the patient, BMS intends to provide the rebate faster than 7 days.
   a. Why is BMS proposing differential treatment for covered entities in different circumstances?
   b. Under what authority does BMS have the discretion to decide when and how covered entities receive the statutory 340B discounted price?
   c. How would BMS propose to implement this for each unique covered entity type that treats its patient populations differently?

4. Under this proposal, if BMS identifies a potential 340B duplicate discount, how will the rebate claim be adjudicated?
   a. What is the timeframe that BMS will process any such adjudication?
   b. What reconsideration or appeals process will BMS implement?
   c. Would BMS automatically deny covered entities' 340B rebate claims if BMS believes a Medicaid rebate was already paid?
   d. Would BMS automatically deny Medicaid rebate claims if BMS believes a covered entity's 340B rebate claims have already been paid?

5. Under this proposal, what are the specific reasons that will lead BMS to reject claims?
   a. Would BMS make these reasons publicly available in advance of adjudication of claims?
   b. Would covered entities receive claim-by-claim information from BMS regarding which claims were rejected and on what basis?
   c. What reconsideration or appeals process would BMS implement to ensure covered entities receive any 340B discounts that are due as required by statute?

6. With respect to the use of pharmacies with which covered entities contract:
   a. Would covered entities need to demonstrate that they purchased individual drugs subject to the rebate claim at wholesale acquisition cost?
   b. Would this process require covered entities to maintain a separate stock of drugs at the contract pharmacy?
   c. If so, how would BMS plan to ensure this process does not functionally deny covered entities access to the 340B price required by the statute given the additional upfront cost and administrative burden for covered entities, particularly low-margin safety net providers?

7. BMS states the 340B rebate will be paid at either the dispensed unit or full package size level upon receipt of a covered entity's data submission.

a. Would covered entities have the option to choose its preference?
b. How would BMS engage with covered entities with respect to these specifics of their prescription drug acquisition and distribution practices?

8. BMS states that it will share data with HRSA to help enhance 340B Program administration, including various reports and metrics. Please explain what data and the frequency of submission of data BMS intends to share with HRSA.

9. Under this proposal, how would BMS treat current unreplenished accumulations?

10. Under BMS's plan, will covered entities would be required to submit claims data to both 340B ESP and the rebate platform?

11. HRSA has received a number of reports of technical and customer service difficulties with 340B ESP. How would BMS ensure covered entities could submit claims without technical difficulties or delays and would be able to access customer support with any issues?

Please send your responses to 340BPricing@hrsa.gov.

Sincerely,

Chantelle V. Britton, M.P.A., M.S.
Director, Office of Pharmacy Affairs

# EXHIBIT 6

HRSA
Health Resources & Services Administration
**Office of Special Health Initiatives**
5600 Fishers Lane
Rockville, MD 20857

November 12, 2024

**BY EMAIL**
Scott Bray
Head of Pricing & Contracting Operations
Sanofi-Aventis US LLC
[redacted]

Dear Scott Bray:

The Health Resources and Services Administration (HRSA) has reviewed the information submitted in your November 1, 2024, correspondence, regarding Sanofi-Aventis U.S., LLC's (Sanofi) proposal to implement a 340B "credit" model on January 1, 2025, for certain hospital covered entities and health center covered entities on March 1, 2025. The 340B statute states that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, *as provided by the Secretary*) to the manufacturer" shall not exceed the statutory ceiling price formula. 42 U.S.C. § 256b(a)(1) (emphasis added). To date, the Secretary has not provided for such a credit model; neither has Sanofi requested approval of the same. Therefore, implementing such a proposal at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval of Sanofi's proposed credit model.

In addition, HRSA requests responses to the following questions:

1. Shifting to a credit model would disrupt how the 340B Program has operated for over thirty years. Sanofi states that, it "is committed to paying the credit before the wholesaler's bill to the covered entity becomes due." The letter further states that Sanofi will offer covered entities the 340B credit within 30 days of the covered entity's wholesale acquisition cost (WAC) order, when the covered entity submits data within 22 days of the WAC order.
   a. Has Sanofi conducted an evaluation of the terms of wholesaler contracts with covered entities to ascertain whether they contain favorable fee terms, including prompt pay terms that require payment within shortened timeframes, which may not align with Sanofi's timeline for paying covered entities the 340B credit?
   b. Has Sanofi conducted an analysis of the extent of the additional burden and/or costs to the affected covered entities, particularly those that are the sole or primary source of health care in a rural or underserved community?
   c. Has Sanofi conducted an evaluation of the impact of this proposal on the scope and breadth of health care access for patients served by affected covered entities?

2. Sanofi states that it will require covered entities to submit credit claims to the credit platform within 30-days.
   a. How did Sanofi arrive at the 30-day cut-off after which a dispense would no longer be eligible for the 340B price?
   b. What other parties, if any, would Sanofi share the claims data with?
   c. What protections and safeguards would Sanofi plan to implement to ensure such information would be used in support of the 340B Program?
   d. What protections and safeguards would Sanofi plan to implement to ensure the privacy and security of such information?
   e. Has Sanofi evaluated if the healthcare encounter data requested is information that covered entities routinely share with third parties and is easily exported from current systems to be able to submit to its credit platform?

3. If Sanofi identifies a potential 340B duplicate discount, how will the credit claim be adjudicated?
   a. What is the timeframe that Sanofi will process any such adjudication?
   b. What reconsideration or appeals process will Sanofi implement?
   c. Will Sanofi automatically deny covered entities' 340B credit claims if Sanofi believes a Medicaid rebate was already paid?
   d. Will Sanofi automatically deny Medicaid rebate claims if Sanofi believes a covered entity's 340B credit claim has already been paid?

4. Sanofi's letter suggests that it intends to assume a quasi-enforcement role of the statutory diversion prohibition and HRSA's 1996 patient definition guidance. Under the guise of preventing diversion, Sanofi has, on its own accord, added an additional element to the 1996 patient definition guidance with its 24-month limit for receiving a healthcare service. Please explain how Sanofi arrived at this 24-month cut-off for determining when an individual is not a patient of a covered entity and the legal justification for this approach?

5. Under this proposal, what are the specific reasons that will lead Sanofi to reject claims?
   a. Would Sanofi make these reasons publicly available in advance of adjudication of claims?
   b. Would covered entities receive claim-by-claim information from Sanofi regarding which claims were rejected and on what basis?
   c. What reconsideration or appeals process would Sanofi implement to ensure covered entities receive any 340B discounts that are due as required by statute?

6. With respect to the use of pharmacies with which covered entities contract:

a. Would covered entities need to demonstrate that they ordered individual drugs subject to the credit claim at WAC?
b. Would this process require covered entities to maintain a separate stock of drugs at the contract pharmacy?
c. If so, how does Sanofi plan to ensure this process does not functionally deny covered entities access to the 340B price required by the statute given the additional upfront cost and administrative burden for covered entities, particularly low-margin safety net providers?

7. Sanofi's letter notes the use of replenishment models by covered entities to manage their 340B inventory. In a situation where the covered entity purchases a Sanofi drug at WAC to replenish a drug previously dispensed to a patient, and subsequently dispenses the replenishment unit thirty-plus days later, how does Sanofi anticipate providing the credit to the covered entity for the replenishment unit before the wholesaler's bill is due on that replenishment unit?

8. Under this proposal, how would Sanofi treat current unreplenished accumulations?

9. Under Sanofi's plan, will covered entities be required to submit claims data to both 340B ESP and the Beacon credit platform?

10. HRSA has received a number of reports of technical and customer service difficulties with 340B ESP. How would Sanofi ensure covered entities could submit claims without technical difficulties or delays and be able to access customer support without any significant issues with the Beacon platform.?

Please send your responses to 340BPricing@hrsa.gov.

Sincerely,

Chantelle V. Britton, M.P.A., M.S.
Director, Office of Pharmacy Affairs

# EXHIBIT 7

HRSA
Health Resources & Services Administration
**Office of Special Health Initiatives**
5600 Fishers Lane
Rockville, MD 20857

January 14, 2025

**BY EMAIL**
Odalys Caprisecca
Vice President, Managed Markets Finance
Novartis Pharmaceuticals Corporation
[redacted]

Dear Odalys Caprisecca:

The Health Resources and Services Administration (HRSA) has reviewed the information submitted in your December 17, 2024, correspondence, regarding Novartis Pharmaceutical Corporation's (Novartis) proposal to implement a 340B rebate model on June 1, 2025, for disproportionate share hospitals. To date, the Secretary has not provided for such a rebate model. The Secretary has neither approved or disapproved Novartis' rebate model. Therefore, implementing such a model at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval of Novartis's proposed rebate model.

In addition, HRSA requests responses to the following questions:

1. Shifting to a rebate model would disrupt how the 340B Program has operated for over thirty years.
   a. Has Novartis conducted an analysis of the extent of the additional burden and/or costs to the affected covered entities, particularly those that are the sole or primary source of health care in a rural or underserved community?
   b. Has Novartis conducted an evaluation of the impact of this proposal on the scope and breadth of health care access for patients served by affected covered entities?

2. Novartis states that it will require covered entities to submit rebate claims to the rebate platform within 30-days.
   a. How did Novartis arrive at the 30-day cut-off after which a dispense would no longer be eligible for the 340B price?
   b. What other parties, if any, would Novartis share the claims data with?
   c. What protections and safeguards would Novartis plan to implement to ensure such information would be used in support of the 340B Program?
   d. What protections and safeguards would Novartis plan to implement to ensure the privacy and security of such information?

3. If Novartis identifies a potential 340B duplicate discount, how will the rebate claim be adjudicated?
   a. What is the timeframe that Novartis will process any such adjudication?
   b. What reconsideration or appeals process will Novartis implement?
   c. Will Novartis automatically deny Medicaid rebate claims if Novartis believes a covered entity's 340B rebate claim has already been paid?

4. Under this proposal, what are the specific reasons that will lead Novartis to reject claims?
   a. Would Novartis make these reasons publicly available in advance of adjudication of claims?
   b. Would covered entities receive claim-by-claim information from Novartis regarding which claims were rejected and on what basis?
   c. What reconsideration or appeals process would Novartis implement to ensure covered entities receive any 340B discounts that are due as required by statute?

5. With respect to the use of pharmacies with which covered entities contract:
   a. Would covered entities need to demonstrate that they ordered individual drugs subject to the rebate claim at WAC?
   b. Would this process require covered entities to maintain a separate stock of drugs at the contract pharmacy?
   c. If so, how does Novartis plan to ensure this process does not functionally deny covered entities access to the 340B price required by the statute given the additional upfront cost and administrative burden for covered entities, particularly low-margin safety net providers?

6. Novartis's letter notes the use of replenishment models by covered entities to manage their 340B inventory. In a situation where the covered entity purchases a Novartis drug at WAC to replenish a drug previously dispensed to a patient, and subsequently dispenses the replenishment unit thirty-plus days later, how does Novartis anticipate providing the rebate to the covered entity for the replenishment unit before the wholesaler's bill is due on that replenishment unit?

7. Under this proposal, how would Novartis treat current unreplenished accumulations?

8. Under Novartis's plan, will covered entities be required to submit claims data to both 340B ESP and the Beacon rebate platform?

9. HRSA has received a number of reports of technical and customer service difficulties with 340B ESP. How would Novartis ensure covered entities could submit claims without technical difficulties or delays and be able to access customer support without any significant issues with the Beacon platform?

Please send your responses to 340BPricing@hrsa.gov.

Sincerely,

Chantelle V. Britton, M.P.A., M.S.
Director, Office of Pharmacy Affairs

# EXHIBIT 8

American Hospital Association™
Advancing Health in America

**Washington, D.C. Office**
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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

# EXHIBIT 9

**August 28, 2025**

**Public Comment on the 340B Rebate Model Pilot Program**
**Submitted by:** The Craneware Group
**Docket No.:** HRSA-2025-14998

To Whom It May Concern:
The Craneware Group appreciates the opportunity to submit comments on HRSA's proposed 340B **Rebate Model Pilot Program** (hereafter, the "Rebate Pilot").

As a long-standing partner to safety-net hospitals, community health centers, and other covered entities participating in the 340B Drug Pricing Program, we work alongside providers who rely on 340B benefits to stretch scarce resources, improve access to care, and sustain essential community services. Any changes to the program must first and foremost protect these patient-focused outcomes.

While we recognize HRSA's efforts to invite stakeholder input, we are deeply concerned that the Rebate Pilot, as currently drafted, is operationally unworkable and may leave hospitals and the communities that depend on them financially at risk and unable to fully meet their mission. We urge HRSA to take additional time to carefully evaluate the potential consequences and make necessary adjustments before finalizing any rebate guidance.

**The Craneware Group's Evaluation of the 340B Rebate Model Pilot Program**
The following analysis reflects The Craneware Group's experience supporting operational, financial, and compliance workflows across a broad spectrum of U.S. healthcare organizations.

To assess the practical implications of the Rebate Pilot, we analyzed data from a representative sample of 17 provider organizations, encompassing 81 covered entities, 573 pharmacies, and 908 contract pharmacy relationships. The dataset covers the period January 1 through June 30, 2025, and focuses on the ten drugs proposed for inclusion in the pilot.

- **Unique prescriptions reviewed:** 95,499
- **Total prescription claims (including refills):** 160,675
- **Listed WAC pricing:** $430,457,141
- **Actual spend under traditional 340B discounting:** $81,758,922.11

**Key Findings**
If these same transactions were processed under the rebate model, Covered Entities in this sample would be required to pay WAC pricing upfront at more than five times higher than current 340B acquisition costs. **That represents a $348.7**

**million increase in short-term cash outlay that providers would need to float while awaiting reimbursement, even under best-case rebate processing timelines.**

This model risks straining provider cash flow, particularly among safety-net hospitals, rural health centers, and other vulnerable entities. **While manufacturers benefit from deferred payout and interest accrual, the financial exposure for covered entities is substantial and deeply concerning.**

**Recommendations**

Considering these findings, The Craneware Group respectfully offers the following feedback for HRSA's consideration:

- **Preserving Operational Continuity and Minimizing Disruption**
  Address the real-world implications of delayed reimbursement, pricing visibility, and cash flow instability introduced by the rebate model.
- **Promoting Standards and Interoperability**
  Ensure the pilot integrates with existing 340B, EHR, and revenue cycle systems, supporting broader national goals of healthcare interoperability.
- **Safeguarding Data Privacy and Streamlining Requirements**
  Limit data demands to what is essential, avoiding unnecessary complexity or duplication that strains provider resources.
- **Supporting Fair Dispute Resolution and Transparency**
  Mandate clear justification for any rebate denial and ensure a timely, transparent resolution process that providers can trust.
- **Preparing for a Dual-Model Environment**
  Anticipate the administrative complexity of managing both rebate-based and traditional 340B discounts simultaneously and provide mitigation strategies to reduce compliance risk and burden.

**The sections that follow expand on each of these points in detail:**

**1. Preserving Operational Continuity and Minimizing Disruption**

The introduction of a rebate-based pricing mechanism — while narrow in scope today — represents a fundamental shift from how the 340B Program has functioned for more than 30 years. Covered entities accustomed to upfront discounts will face new timing, reconciliation, and reporting burdens that directly threaten the patient benefits 340B participation makes possible. For many safety-net providers, these benefits fund healthcare services, medication access, patient assistance programs, and essential community services.

A critical operational concern is the absence of the 340B price through wholesaler account price catalogs under the rebate model along with the lack of bulk access to 340B ceiling prices. Without visible 340B pricing flags, covered entities and their third-party administrators (TPAs) cannot confirm drug eligibility in real time. Because the 340B ceiling price is not available to TPAs, providers would be unable to validate purchases, ensure compliance, or reconcile rebate payments accurately — increasing compliance risk and delaying or eliminating savings that support vulnerable patients and communities.

We urge HRSA to:

- **Require that 340B pricing remain visible** in wholesaler account price catalogs for rebate-eligible drugs during the pilot or grant access to the full 340B ceiling price data-set through exports to allow systematic validation of 340B prices and rebate payment.
- **Restrict advance WAC purchase requirement** allowing WAC purchase to occur at anytime in relation to service date rather than requiring a WAC purchase to have occurred prior to the 340B claim being dispensed.
- **Allow 340B adjudication to occur prior to Medicare Part D (MFP) rebates** sustaining maximum 340B benefit to Covered Entities and operational efficiencies.
- **Preserve operational efficiency** by ensuring rebate platforms align with the systems providers already use, such as claims data feeds, TPA connections, or wholesaler account structures, to avoid duplicative work and manual reconciliation.
- **Monitor cash flow and workload impacts** on pharmacy and finance teams, with particular attention to Disproportionate Share Hospitals (DSH), rural hospitals, and Federally Qualified Health Centers (FQHCs).
- **Provide implementation support or grants** for rural and resource-constrained entities.
- **Issue timely contract pharmacy guidance** and clarify whether contract pharmacies will retain access under the pilot. Clarification is required as to whether manufacturers must allow multiple contract pharmacies, which are currently denied through unilateral manufacturer contract pharmacy restriction policies.
- **Address the cash flow crunch** created by wholesale acquisition cost (WAC) purchasing. For example:
    - **Establish an interim payment or rebate prepayment model to limit provider exposure to prolonged reimbursement delays.** This mimics how interim payments or draw-downs are used in other CMS programs and would keep providers from carrying 100% of the financial risk.
    - **Mandate that rebates be paid within a defined, enforceable timeframe with interest penalties for delay.** Create a defined standard that ensures manufacturers process rebates with urgency, just as providers are expected to dispense and report on tight deadlines.
    - **Include manufacturer reporting requirements that disclose the average float period and cash impact on covered entities.** We believe HRSA should see in black-and-white that providers will be floating millions of dollars for much longer than 10 days.
    - **Provide technical assistance, risk modeling tools, and targeted financial support for small and rural providers facing disproportionate cash flow exposure.** Some providers may need bridge support or at least structured forecasts to prevent disruption of patient care due to cash flow issues.
- **The most significant hidden cost of the rebate model for covered entities is the time value of money — the financial impact of advancing millions in drug spend while waiting for reimbursement.** HRSA should make clear that manufacturers must compensate providers for this burden, consistent with the regulation's stated intent that no administrative costs be passed on to covered entities.

Even short delays in receiving rebates reduce the resources available for patient care. For a rural hospital with limited staff and tight margins, a 30-day delay can mean postponing medication purchases, scaling back covered entity patient assistance programs, or cutting uncompensated care. These outcomes run counter to the mission of the 340B Program and jeopardize the stability of our nation's healthcare safety net.

**2. Promoting Standards and Interoperability**

We support the requirement that manufacturers bear all IT and administrative costs related to the rebate model. However, to truly reduce provider burden and variability, and to protect patient access, HRSA should:

- Establish baseline data standards and technical specifications for the required IT platforms at the outset of the pilot, not after implementation.
- Require systems to integrate with existing 340B tools and revenue cycle systems to enable seamless execution and avoid undoing years of progress toward national interoperability and value-based care:
    - **Avoid shifting the cost of operational system changes onto covered entities.** Most providers have already configured their EHRs, revenue cycle systems, and 340B platforms to comply with existing standards and workflows. Supporting the rebate model may require significant reconfiguration, system customization, or third-party integration; yet the guidance does not specify how covered entities will be reimbursed for these expenses. HRSA should require manufacturers to cover these costs, consistent with the stated intent that providers bear no costs under the pilot.
    - **Align with national policy goals**. The shift toward a value-based healthcare economy depends on connected, data-driven systems that reduce administrative burden and improve care coordination.
    - **Prevent workflow disruption**. Lack of integration would force providers into duplicative or manual processes, recognizing indirect costs but having no clarity on how these costs will be borne by manufacturers, exposing them to increasing compliance risk, delayed rebate payments, and potentially limiting funds for patient services.
    - **Support scalability and vendor choice**. Integration ensures providers can continue using trusted technology partners rather than being locked into manufacturer-selected platforms.
- Develop a vendor-neutral reporting framework to ensure transparency, scalability, and provider choice across different covered entity types and sizes.

Without common standards and interoperability from day one, providers will face increased administrative complexity, higher compliance costs, and greater risk of error. These outcomes directly counter to the pilot's stated goals. The result would not just be operational inefficiency; it could mean delayed patient care and diminished access to lifesaving medications. Interoperability is not optional. It is foundational to success.

Past federal initiatives, such as the initial stages of the EHR Incentive Programs ("Meaningful Use"), demonstrated that delaying interoperability standards until after rollout significantly increases provider burden, implementation costs, and the time required to realize intended program benefits — lessons that should inform the 340B rebate pilot from the start.

**3. Safeguarding Data Privacy and Streamlining Requirements**

We appreciate HRSA's guardrails on data privacy and limiting the required fields for rebate submission. However, there is growing ambiguity between the original 340B rebate guidance, which clearly identifies a maximum of 11 data fields, and the HRSA FAQ, which permits manufacturers to request additional fields in their individual pilot plans with justification. This introduces significant risk. If each manufacturer requests a different set of fields or formats, covered entities will be forced to build multiple custom processes and technologies to comply — a costly and time-intensive undertaking. **This complexity cannot be implemented in 60 days, particularly for providers managing limited resources and multiple vendor integrations.**

In addition, even standardized fields (such as RX number, NDC, and prescriber ID) vary across systems and provider types. If manufacturers enforce rigid formatting or deny rebates based on non-substantive discrepancies in these fields, covered entities may experience avoidable delays and claim denials, creating downstream financial gaps and operational inefficiencies.

We recommend:

- **Clarifying that only the 11 fields defined in the regulation are required** for all manufacturers, unless HRSA specifically approves additional elements for **all** pilot participants.
- **Requiring uniform formatting standards and validation logic** across manufacturers to prevent fragmentation and reduce the burden on covered entities.
- **Ensuring that any additional fields proposed by manufacturers are subject to HRSA review and public comment**, and that providers are given adequate time and technical guidance to implement changes.
- **Providing a standardized, HRSA-approved data guide**, including submission, adjudication, and reconciliation specifications to promote consistency and minimize delays.

Every additional data requirement takes time and attention away from patient care. Unnecessary variation across manufacturer requirements will result in avoidable claim rejections, delayed rebates, and added administrative overhead — all of which undermine the 340B Program's mission to stretch scarce resources in support of vulnerable patients.

**4. Supporting Fair Dispute Resolution and Transparency**

The Rebate Pilot's explicit restrictions on rebate denials for diversion or duplicate discount concerns are a strong foundation. To ensure these protections translate into uninterrupted patient care, HRSA must require:

- **Detailed, standardized denial documentation.** Manufacturers should provide written notice for any denied rebate, citing a specific reason from a defined list of allowable grounds, and offer a time-bound appeals process. This will allow covered entities to act swiftly, resolve disputes, and protect patient services.
- **Real-time rebate status visibility.** The rebate IT platform must include real-time financial tracking and reconciliation capabilities. Providers need to know when and how rebate funds are flowing because those dollars support direct care, not overhead.
- **Clear guidance on impacted patient programs.** If a rebate is denied, HRSA must clarify how providers should continue operating 340B-funded medication access or patient assistance programs. Without such guidance, safety-net providers may be forced to reduce services mid-treatment due to reimbursement uncertainty.

When rebates are delayed or denied without cause, the result is not just an administrative burden -- it's fewer medications, fewer outreach programs, and fewer care options for patients in need.

To safeguard fairness and transparency, HRSA should implement a robust oversight and accountability framework that includes:

- **Consequences for delayed payments.** Providers must not absorb the financial burden of late or missing rebates. Timely payments should be mandatory, with penalties for delays, consistent with existing 340B civil monetary penalties.
- **Required manufacturer reporting.** HRSA should mandate transparent reporting from manufacturers, including:
    - Total rebates paid and rejected, by covered entity
    - Rejection categories with reason codes
    - Average days to payment
    - Number of unresolved disputes
- **Enforceable penalties for non-compliance.** Rebates that are wrongfully withheld should carry meaningful consequences, just as traditional 340B overcharges do.
- **A neutral, HRSA-led dispute resolution process.** When internal appeals fail, providers must have access to a timely, binding third-party resolution mechanism. Without this, manufacturers retain unchecked control over the flow of rebate funds.

**5. Preparing for a Dual-Model Environment**

During the Rebate Pilot, covered entities will likely operate under both the traditional 340B discount model and the rebate-based model simultaneously, introducing risk of confusion, administrative burden, and compliance exposure.

We urge HRSA to:

- **Issue clear guidance on managing dual models**, including how covered entities can track rebate eligibility across purchasing channels.
- **Clarify whether manufacturers may apply their own contract pharmacy restrictions under the Rebate Pilot**, recognizing that such restrictions further limit patient access, especially in rural and underserved communities.
- **Evaluate scaling the rebate model to other drug classes only after robust performance metrics, stakeholder feedback, and unintended consequences are fully reviewed**. Operating under two models will increase complexity and compliance risk. Without clear, practical guidance, well-intentioned providers could face audit findings or penalties, jeopardizing their ability to participate in the program and maintain access for their patients.

**In closing**, The Craneware Group is committed to supporting the healthcare providers who rely on the 340B Program to sustain access, affordability, and care delivery in vulnerable communities across the US. As a technology partner with deep experience in compliance and operational integration, we will do everything we can to help our customers understand and adapt to these proposed changes.

That said, we must be clear: the current structure of the 340B Rebate Model Pilot presents significant challenges. The implementation timeline is too short, key components remain undefined, and the burden on covered entities is disproportionate. Without greater specificity, reasonable lead time, and enforceable guardrails on manufacturer behavior, this pilot undermines the very outcomes the 340B Program was designed to protect.

We urge HRSA to provide additional clarity, extend the timeline for implementation, and include stronger protections to ensure manufacturers are held accountable. These steps are critical to ensuring that any transition to a rebate model is feasible, fair, and aligned with the mission of the 340B Program.

Sincerely,

***Lidia Rodriguez-Hupp***
Chief Customer Officer
*The Craneware Group*

# EXHIBIT 10

Office of the Chief Executive Officer

UVA Health

**September 5, 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: Comments on HRSA's Proposed 340B Rebate Model Pilot Program** (HHS Docket No. HRSA–2025–14619)

Dear Administrator Engels:

On behalf of UVA Health, I write to express our strong opposition to HRSA's 340B Rebate Model Pilot Program for drugs subject to Medicare drug price negotiations. The model increases the price of drugs that hospitals must purchase for patient care and imposes significant administrative and operational costs. As a result, it runs counter to the intent of the 340B Program which allows hospitals to stretch scarce federal resources to reach more patients and provide more comprehensive services. **We urge HRSA to withdraw this proposed model immediately.**

**The Importance of the 340B Program to UVA Health**

The 340B Program is critical to our health system, which includes three 340B disproportionate share hospitals: UVA Health University Medical Center, UVA Health Prince William Medical Center, and UVA Health Culpeper Medical Center.

- **UVA Health University Medical Center** is an 800-bed public safety net hospital and academic medical center in Charlottesville, Virginia, that also serves as a rural referral center.
- **Culpeper Medical Center,** a small rural hospital, and **Prince William Medical Center** in Manassas, serve patients in northern Virginia.

In FY25, UVA Health's reduced drug expenditure under 340B was $370 million. Without the program, our total drug expense would

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have exceeded $970 million. The savings generated by 340B allow UVA to reinvest in programs that ensure economically disadvantaged patients have access to specialized care, closer to home. A central priority is ensuring access to an affordable and adequate supply of medications, which is fundamental to patient care.

Through 340B, UVA Health is able to:

- Operate 10 community pharmacy locations in Charlottesville, Augusta, Zions Crossroads, and rural Nellysford, VA, including the region's only 24/7 outpatient pharmacy;
- Offer the UVA Prescription Discount Program at all retail pharmacies, providing generic medications at significantly reduced costs—many available for $4 per month;
- Integrate pharmacists at the bedside, in clinics, and within patient assistance programs to improve medication access, adherence, and coordination of care, ultimately reducing ED visits and hospital readmissions;
- Provide free or discounted medications to economically disadvantaged patients on a sliding scale; and
- Contract with external and specialty pharmacies to extend access to critical therapies based on patient location.

Without the 340B Program, many of these services, among others, would be significantly curtailed due to ballooning drug costs.

**Background on the Proposed Pilot**

Under the proposed pilot rebate model:

- Ten drugs identified under the 2026 Medicare Drug Price Negotiation Program would be subject to rebates;
- Hospitals would be required to purchase these drugs at the wholesale acquisition cost (WAC) rather than the 340B ceiling price;
- After dispensing, hospitals must submit rebate claims within 45 days, with manufacturers required to pay rebates within 10 days; and
- Manufacturers would be prohibited from denying claims based on duplicate discounts or diversion.

## Financial Impact

UVA Health estimates that purchasing these 10 drugs at WAC would require an additional $66 million annually. This would tie up critical cash flow until rebate claims are processed and paid. Depending on dispensing dates and manufacturer response times, cash flow could be delayed for 60 days or longer—an untenable position for many hospitals, particularly rural or safety-net facilities with limited margins.

We are also concerned that the model relies heavily on manufacturers' self-governance, leaving covered entities with little recourse for denied or delayed claims. Given manufacturers' financial incentives, this creates a significant risk of late or disputed rebate payments.

If HRSA proceeds, the model must include clear safeguards:

- Prohibit manufacturers from using contract pharmacy restrictions or inventory allocations to deny rebates;
- Ensure contract pharmacy dispenses remain eligible for rebates;
- Clarify that drug manufacturers should not deny 340B rebates for reasons unrelated to the 340B drug discount program (e.g., voluntary rebate agreements that occur between drug manufacturers and pharmacy benefit managers); and
- Establish a formal, time-bound appeals process and impose civil monetary penalties for non-compliance or delayed rebate payments.

## Administrative Burdens on Covered Entities

While HRSA indicates that manufacturers will bear certain administrative costs, the proposal does not adequately address or include the administrative and operational costs that will be borne by hospitals to implement the model. Covered entities will face new expenses for:

- Personnel to manage manufacturer-specific processes.
- Systems for tracking and reconciling rebate payments.

- Collating and submitting data across multiple manufacturer platforms.

Because manufacturers may use different vendors for data submission, covered entities could be forced to execute numerous business associate agreements and perform data security assessments for each platform. As a state-owned institution, UVA is subject to the Virginia Public Procurement Act, and past experience with 340B ESP showed that such processes can take more than 12 months to complete. In accessing 340B ESP, there was an extensive contract negotiating process that was met with a lack of engagement and partnership with 340B ESP's legal counsel. If there are multiple platforms to use in the rebate model pilot program, UVA Health expects that similar contract negotiations and roadblocks would arise. As such, UVA Health urges HRSA to clarify that covered entities' costs associated with the model will also be borne by the manufacturers, not hospitals.

**Medicaid Billing Complications**

Further, the model creates uncertainty in Medicaid Fee-for-Service billing. In Virginia, covered entities must pass savings on to the Medicaid program by billing at actual acquisition cost (AAC). Under the pilot, drugs would be purchased at WAC but reported at the 340B ceiling price, creating reconciliation challenges. In practice, this may require manual rebilling if rebates are denied, creating additional administrative costs and potential compliance risks.

If UVA Health realizes fewer savings under the rebate model, the Commonwealth itself will face increased Medicaid costs—a financial burden that should not be overlooked, especially given proposed federal Medicaid reductions.

**Other Operational Concerns**

The pilot appears to apply to both pharmacy-dispensed and clinic-administered drugs. Many required data elements are not captured in medical billing systems, creating a risk that incomplete submissions could be used to deny rebates. For this reason, we urge HRSA to narrow the pilot to **pharmacy-only claims** for the 10 identified drugs.

Office of the Chief Executive Officer

UVA Health

**Conclusion**

The proposed rebate model would impose significant financial strain, administrative burden, and operational complexity, reducing the resources available to UVA Health and other hospitals to serve their vulnerable patients.

We are deeply concerned that such a model would further erode HRSA's authority to administer the 340B Program, shifting governance to drug manufacturers. We strongly urge HRSA to withdraw the proposed rebate model. At minimum, HRSA should redesign the program to reduce the model's scope to pharmacy-dispensed drugs and ensure that covered entities' administrative and operational costs be borne by the manufacturers. Such changes would allow hospitals to continue to use their scarce resources for patient care, rather than complex rebate administration.

Thank you for your consideration of these comments and for your commitment to ensuring access to care for underserved patients.

Sincerely,

DocuSigned by:
Wendy Horton
69C73AC5C491474...

Wendy Horton, PharmD, MBA, FACHE
CEO, UVA Health University Medical Center

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# EXHIBIT 11

SANFORD HEALTH

Secretary Robert F. Kennedy, Jr.
Department of Health and Human Services
200 Independence Ave., SW
Washington, D.C. 20201

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

Submitted via https://www.regulations.gov/
HHS Docket No. HRSA– 2025-14998

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

Dear Administrator Engels,

I am writing on behalf of Sanford Health to provide comments on the 340B Rebate Model Pilot Program announced by HRSA on July 31. We respectfully urge HRSA to withdraw the proposal as currently presented and instead initiate a meaningful engagement process with stakeholders to identify practical solutions to the challenges facing the 340B program. This collaborative approach would better support the program's mission of ensuring access to high-quality health care for all Americans.

Sanford Health is the largest rural health system in the United States and is deeply committed to transforming the health care experience while expanding access to exceptional care across the heartland. Headquartered in Sioux Falls, South Dakota, our nonprofit, integrated health system employs 53,000 people and serves more than 2 million patients and nearly 425,000 health plan members throughout South Dakota, North Dakota, Minnesota, Wyoming, Iowa, Wisconsin and Michigan's Upper Peninsula. Our network includes 56 hospitals, 288 clinic locations, 147 senior care communities, 4,000 physicians and advanced practice providers and nearly 1,500 active clinical trials and studies. Through our virtual care initiative, patients have access to 78 specialties, helping bridge gaps in care across rural communities.

The 340B program is a critical resource that enables safety net providers like Sanford Health to maintain and expand health care infrastructure in rural areas. We are committed to finding solutions to ensure the long-term sustainability of the program, but the rebate model under consideration does not achieve this goal. Instead, it would undermine the core tenets of the program and threaten access to high-quality health care for millions of Americans and represents an existential threat to the 340B program's ability to function properly and meet its mission.

**A Rebate Model Runs Counter to the Intent of the Statute and Creates an Irreconcilable Power Imbalance**

As proposed, the 340B Rebate Model Pilot Program ("pilot") grants drug manufacturers sweeping and disproportionate control over the 340B program. It strips away essential protections for covered entities, including hospitals and community health centers and exposes both patients, and the care networks they depend on, to serious existential threats.

Most notably, the pilot places nearly all operational and discretionary authority in the hands of pharmaceutical manufacturers. Covered entities are required to participate in the pilot if they wish to remain in the 340B program, yet they are offered no meaningful safeguards in return. The proposal outlines only the most basic requirements for what covered entities must submit to manufacturers, while offering vague and insufficient guidance on how manufacturers should process those claims. There is no substantive appeals process for denied claims, leaving covered entities vulnerable and without recourse.

This imbalance creates a system in which manufacturers are not held accountable. Without clear expectations and enforcement mechanisms from the Department of Health and Human Services, manufacturers are likely to exploit the lack of oversight to their advantage. The pilot program's language suggests that manufacturers should act in "good faith" and that non-compliance could result in removal from the program, but it fails to define what constitutes good faith or what specific actions would warrant removal. Non-existent compliance expectations for drug manufacturers is an obvious detriment to covered entities. Why should covered entities be expected to trust a process that has historically been weighted against them?

Additionally, we are concerned about the publication of frequently asked questions by HRSA's Office of Pharmacy Affairs around August 18. These FAQs contain material information that significantly alters the understanding of the original proposal released on July 31. The timing and content of these updates suggest that HRSA and OPA may have made key decisions without fully considering input from covered entities and the patients who stand to be most affected.

Moreover, HRSA has not provided a clear rationale for why a rebate model is necessary. Drug manufacturers argue that rebate models help prevent statutory violations such as diversion and duplicate discounts. However, the pilot explicitly states that manufacturers may not deny rebates based on allegations of non-compliance. The appropriate mechanism to address concerns about diversion and duplicate discounts is through audits and administrative dispute resolution, as outlined in the 340B statute. This contradiction between the stated goals of the pilot and its actual provisions undermines the legitimacy of the proposal and raises serious questions about its intent and effectiveness.

**The Rebate Model Threatens the Financial Stability of Safety Net Providers**

In the current structure, Sanford Health purchases medications at the 340B price, receiving an upfront discount that helps maintain financial stability and ensures continued access to care. The proposed rebate model would require covered entities to purchase drugs at the wholesale acquisition cost, which is the highest price manufacturers offer and then wait for a rebate to be issued. This shift presents significant financial challenges.

Pharmacies must maintain adequate inventory to meet patient needs and paying the full wholesale price upfront would dramatically increase inventory costs. This would reduce the financial reserves available to covered entities and strain their ability to operate effectively. Concerns about cash flow have already been raised in connection with Medicaid Drug Rebate Program rebates and layering 340B rebates on top of that would only worsen the situation.

Additionally, medications are not always dispensed immediately after purchase. For drugs that are used infrequently, several months may pass between the time of purchase and the time of dispensing. Under the rebate model, covered entities would be required to absorb the higher upfront cost for an indefinite period.

In its current form, the pilot will be effectively owned, operated and controlled by the drug manufacturers, leaving covered entities at the mercy of unilateral policies imposed by these companies. Even though the pilot states that manufacturers cannot deny rebates based on own policy restrictions, we know that manufacturers have a history of unilaterally imposing requirements under the guise of "program integrity." With manufacturers holding full control over the rebate review and issuance process, there is no guarantee that rebates will be issued fairly or consistently. The pilot will allow manufacturers to weaponize the alternative dispute resolution process by leveraging it to further delay rebates and/or discourage covered entities from pursuing the accrued rebates due to the complexities and burden associated with pursuing such a claim. The dispute process is purposely complicated and burdensome and holds potential to ruin covered entities with legal fees, lengthy holding patterns and withholding financial discrepancies.

This financial burden is unsustainable for many 340B providers, especially those already facing economic instability. Though the notice requires manufacturers to assure that no costs for data submission or additional administrative costs are passed to covered entities, there is no definition as to what administrative costs are included or how a covered entity may receive reimbursement for such costs. The proposed model introduces uncertainty and risk into a program that is meant to support the financial viability of safety net providers and the communities they serve.

**The Proposed Pilot Project Is a Pilot in Name Only**

The notice accompanying the pilot program states that rebate models could fundamentally shift how the 340B Program has operated for more than 30 years. This acknowledgment underscores the significance of the proposed changes, yet covered entities have been given only a few months to prepare for an entirely new system. While participation in the pilot is voluntary or by invitation for drug manufacturers, it is mandatory for all covered entities, without exception. This imbalance in participation is deeply concerning and reflects poor policy design.

Although the pilot is described as a trial period for a new methodology and structure, it appears to be finalized with little opportunity for meaningful feedback or revision before its implementation. A pilot program without a clearly defined end point creates the risk of ongoing abuse and mission creep, often evolving into long-standing or even permanent programs beyond its original intent. There is no indication that HRSA intends to seek input on the pilot's performance after it begins, nor is there a clear plan to evaluate its impact. The absence of

defined metrics to assess success or failure for manufacturers, covered entities, or patients further undermines the credibility of the pilot. Without a clear end point or a framework for learning and refinement, it is difficult to view this as a true pilot. Instead, it appears to be a permanent shift that primarily benefits manufacturers. At a minimum, HRSA should clearly define the indicators and benchmarks that will determine whether the rebate model is discontinued or adopted as a replacement for the current 340B structure.

Additionally, the enforcement mechanism outlined in the notice to ensure manufacturer compliance with the pilot is unlikely to be carried out in practice. Period. Terminating a manufacturer's PPA agreement does not provide a meaningful solution for the population we are aiming to support, as it would ultimately reduce access rather than improve compliance. Because this option of withdrawing the PPA is neither realistic nor practical, there should be additional, proportional repercussions tied to failures. These should be designed to encourage corrective action and accountability without undermining the very goals the 340B program is intended to achieve.

**Additional Administrative Burdens Will Overwhelm Many Covered Entities**

The administrative demands of the proposed pilot are especially burdensome for small, rural hospitals and providers. The current framework allows each drug manufacturer to establish its own process for making the 340B price available under the pilot. Despite some general guidelines, manufacturers are permitted to use their own IT platforms and may require different sets of data for rebate submission. This fragmented approach means hospitals will have to navigate multiple systems and processes, significantly increasing complexity and workload. On top of the complexity associated with the rebate model, covered entities will be expected to maintain their current 340B program requirements, effectively requiring covered entities to manage two separate workflows to capture 340B savings.

Hospitals would be required to submit data to platforms owned or operated by drug companies or their affiliates, agents or vendors. These platforms are not neutral and there is a real risk of conflicts of interest or misuse of sensitive data. Furthermore, the pilot is silent on what the data protections should look like for participants in this program. Manufacturers are not HIPAA covered entities and it's unclear whether covered entities can lawfully provide the data demanded. Additionally, the platforms that covered entities have so far been asked to submit data do not have reasonable terms established through an arms-length transaction. Instead, they are dictated by the platform who will inherently favor their clients' (manufacturers) interests. Private health information deserves the strongest levels of protection possible. Silence in the notice on how data protections will be incorporated into the overall structure of the program is a serious gap that cannot be left unaddressed. Standards should not be forced on covered entities while manufacturers avoid accountability and liability. Covered entities of all sizes are committed to responsible data management and risk mitigation. The lack of clear lines of responsibility for data security, including financial components, and responses to potential breaches must be addressed.

Rural providers especially often lack the staff and resources to manage these administrative requirements. They may be forced to hire additional personnel or divert existing staff from

patient care to manage the demands of multiple rebate systems. This shift would strain already limited resources and compromise the quality of care.

**Conclusion**

In closing, the proposed pilot program contains deep and systemic flaws that make effective or responsible implementation impossible within the timeline outlined in the July 31 notice. The scope and complexity of the changes, combined with the lack of clarity, oversight and infrastructure, present an unmanageable burden for covered entities, especially rural providers already operating under financial strain. For these reasons, we strongly urge HRSA to abandon the 340B Rebate Model Pilot Program in its entirety.

If HRSA chooses to proceed with this ill-advised initiative, it is imperative that drug manufacturers be held to the same standards and expectations as covered entities. The current proposal gives manufacturers disproportionate control without corresponding accountability. We call for immediate and substantial revisions to the pilot framework, including clear definitions of manufacturers' responsibilities, robust oversight mechanisms and regular auditing to ensure compliance. Additionally, HRSA must establish transparent parameters for the pilot's duration, measurable evaluation criteria, and a structured timeline for program refinement based on stakeholder feedback.

Covered entities must also be protected from the significant financial, operational and administrative burdens this pilot would impose. As the proposal stands now, covered entities will bear the burden of additional operating costs, hiring costs, increased IT costs, increased inventory purchasing costs, the cost of reimbursement delays and more. This undefined list of additional costs will ultimately destroy rural providers and leave patients abandoned. A full accounting of these costs is essential, along with a mechanism to ensure fair and adequate reimbursement for the investments required to comply. Without these safeguards, the pilot risks destabilizing the very providers the 340B program was designed to support, ultimately threatening patient access to care in vulnerable communities.

The pilot as currently proposed has no positive impact on covered entities or patients. As the agency itself notes in the notice, the proposed pilot is a result of manufacturers seeking alternative mechanisms to manage the 340B program. It is clear based on manufacturer behavior of the last several years that they are not interested in improving the 340B Program or merely preventing duplicate discounts. Rather they are seeking mechanisms to thwart efforts of covered entities to stretch scarce resources to reach more patients and provide comprehensive services.

We appreciate the opportunity to share our perspective on this important issue. Should you have questions or wish to discuss these concerns further, please feel free to contact Jesse Breidenbach, Vice President of Pharmacy (jesse.breidenbach@sanfordhealth.org), or Corey Brown, Senior Vice President of Government Affairs (corey.brown@sanfordhealth.org).

Sincerely,

Martha Leclerc
Vice President, Corporate Contracting
Sanford Health
Martha.Leclerc@sanfordhealth.org

# EXHIBIT 12

UNC HEALTH®

***General Response to Proposal*** –

- UNC Health would like the 340B rebate proposal to define the term duplicate discount and ensure applies only to Medicaid FFS as defined by statute. Manufacturers and endorsed IT platforms by manufacturers have loosely applied the term to Medicaid MCO and commercial payer rebates.
- Seeking comments by September 8th but manufacturers must submit plans by September 15th – not enough time to meaningfully respond to comments

***RFI –*** *Are there any additional flexibilities to maximize efficiency and efficacy for participating manufacturers that should be considered in the pilot design?*

- We would like to see HRSA or CMS publish a centralized list of Medicaid plans (BIN/PCNs) and Medicare plans (BIN/PCNs) to decrease the risk of a covered entity inadvertently causing a duplicate discount with Medicaid and to decrease the risk of overlapping MFP and 340B rebates.

***RFI –*** *Are there any additional safeguards to mitigate adverse, unintended impacts for covered entities that should be considered in the pilot design?*

- UNC Health is advocating for this pilot to be limited to retail claims only – we believe that is the intent based on the 11 data elements manufacturers can utilize in their proposal, but this is not explicitly stated in the proposal.
- Additionally, we would like to advocate that only the data elements outlined in the proposal be in scope for the rebate pilot. Prior attempts by manufacturers to implement rebates in the mixed-use setting required data elements that are not readily accessible for covered entities and are not included in current third-party administrator (TPA) data.
- We would like the proposal to further define specifically when a claim can be denied a 340B credit by a manufacturer. We are concerned that the term duplicate discount will be extended to commercial payer rebates, causing covered entities to be denied 340B rebates if a manufacturer has already recognized a payer's claim on that same prescription for rebate purposes.
- The current proposal does not specifically address drugs that are not eligible for 340B but have a lower 340B price than MFP. These claims should qualify for the MFP rebate in this case but there may not be a way to submit these claims if all claims for that drug from a covered entity are rejected by the MTF.

- UNC Health encourages the use of one IT platform, with standard reporting requirements and claims reconciliation processes (package level vs unit level) across all manufacturers. This should be operated by a neutral third party with agreeable terms and conditions for covered entities. The predominant platform that has been proposed by manufacturers, Beacon, works on behalf of manufacturers and inherently will have their best interest at heart.
- The IT platform(s) endorsed should have agreeable terms and conditions for covered entities. In its current state, these terms of use are unilateral and give up all rights for the covered entities. Some examples from Beacon include –
    - The company does not warrant that you will be able to access or use Beacon at the times or locations of your choosing,
    - You may not use automation to access their platform as a covered entity,
    - They are not liable for HIPAA or security breaches,
    - Arbitration – Second Sight determines if it goes that route and chooses the company to use,
    - You waive the right to a jury trial, and
    - All claims and disputes must be arbitrated or litigated on an individual basis – not on a class basis and claims of more than one user cannot be arbitrated or litigated jointly or consolidated with other users.
- We advocate for contract pharmacies to be restored for covered entities. Without protections and with claims data, manufacturers may further restrict contract pharmacies for covered entities since ESP claims data would no longer be needed.
- Further guidance should be provided on when a manufacturer audit will be approved and the scope of the audit and on the administrative dispute resolution (ADR) process for when disputes arise and the manufacturer wants to pursue additional action.
- Additional consideration should be given for covered entities managing multiple IT platforms between the IRA (MFP/MTF facilitator) and multiple 340B rebate IT platforms. This will add to administrative burdens given the lack of standardization to systems, processes, payments, reconciliations, and data elements. We encourage a streamlined and standardized approach to both initiatives.

***RFI –*** *Are there any additional data or reporting elements that should be required to improve implementation and evaluation of the pilot?*

- UNC Health advocates for the following data elements to be tracked during this pilot period –
    - Change in volume of 340B purchases by covered entities pre- vs. post-pilot
    - Rebate denial rates and reasons
    - Increased costs to covered entities (labor, denials, increased WAC purchases, increased third-party administrator (TPA) costs)
    - Change in the volume of manufacturer audits of covered entities pre- vs. post-pilot and the change in data request lists (DRL) involved in these audits.

***RFI –*** *Are there any potential implementation issues not yet sufficiently accounted for in the pilot design (e.g., logistical or administrative burdens)?*

- This model no longer allows for clean sites that strictly serve 340B patients to continue to prospectively purchase 340B drugs for their patients. This will add financial strain to those sites that utilize this model, such as oncology and non-oncology infusion sites, since they will have to buy all inventory at WAC and wait for a rebate. The WAC costs of these drugs can be significant compared to 340B.
- This will adversely affect covered entities not subject to GPO prohibition, such as the Rural Referral Centers and Critical Access Hospitals, since they will not be able to buy these drugs at GPO and will need to make the initial purchase at WAC. Additionally, a denied rebate will result in increased costs since they will have purchased the drug at WAC rather than GPO.
- Covered entities are expected to bill Medicaid the actual acquisition cost of the drug. We will not know this information at the time of billing, thereby causing difficulty in continuing to carve-in Medicaid at sites. Additionally, denied rebates will cause sites to be under-reimbursed if they continue to carve-in Medicaid. This could cause sites to start to carve-out Medicaid if they receive a significant rate of denials for 340B rebates by the manufacturers.
- Without the restoration/protection of contract pharmacies included in this proposal, manufacturers may stop allowing for contract pharmacy designations within ESP since they will now have claims data. This could increase the financial burden experienced by covered entities.

- It will be administratively burdensome, and duplicative, for covered entities to submit claims data in ESP and in the rebate IT platform.
- This proposal will make it very difficult for small and rural covered entities to continue participation in the 340B program given the added administrative burden to submit claims and reconcile rebates.
- If the 340B rebate proposal is enacted, requirements and best practices endorsed by HRSA for self-auditing on claims should be revisited. Depending on the scope of the pilot, this would create duplicative auditing by the manufacturer for 340B credit, as well as by the covered entity.
- This rebate pilot may cause additional financial harm to covered entities due to denied 340B claims at contract pharmacies. If the claim is denied by the manufacturer, the covered entity would likely still need to replace the drug for the contract pharmacy at WAC rather than 340B.
- The claim reconciliation process will add additional administrative burden to covered entities. MFP claims reconciliation will flow through the MTF/MTP platform, with payment for rebates going to the dispensing pharmacy, whereas the 340B rebate will utilize multiple different IT platforms, requiring multiple claims reconciliations that will need to be manipulated to attribute the lump sum payment to the covered entity back to individual claims within dispensing pharmacies.
- The reliance on the ADR process to resolve disputes with manufacturers will add costs and administrative burden to covered entities if they decide to pursue this option.
- The rebate proposal allows manufacturers to audit covered entities without guardrails on what those audits may be approved for by HRSA. This likely will result in more manufacturer audits of covered entities and increased administrative burdens by covered entities. Several of these audits have resulted in litigation, adding additional costs to covered entities.
- Covered entities will experience a negative impact to their cash on hand due to the need to buy these drugs at WAC and wait for a 340B rebate.
- The rebate model may be detrimental to our wholesaler contract since we are penalized for not meeting certain performance metrics tied to maintaining our non-WAC purchases. This could result in a decrease in our cost minus, resulting in an additional increase in our drug expense outside of the cash on hand impact and risk for denied 340B rebates.
- For rebates paid at the package level, it will take a long time for drugs not utilized often to reach a full package size and receive the 340B rebate. This will adversely

smaller, rural hospitals within health systems that rely on a centralized service center (CSC) to help offset these high inventory costs.

***Comments on the General Requirements of the Rebate Model Pilot***

- Without an endorsed IT platform, it will be difficult for covered entities to review terms of use and contract with those platforms within 60-days of the manufacturer specific plans being released.
- Historically, the terms and conditions of IT platforms hired by manufacturers were unfavorable for covered entities and they have not accepted any redlines to their terms.
- The liability for HIPAA and security breaches for the existing IT platforms endorsed by manufacturers rests with the covered entity, although no choice in the platform is given. UNC Health advocates for a neutral third-party to manage the IT platform.
- There are concerns about downtime for the IT platform causing negative impacts to covered entities. As proposed, there would be no protections for covered entities and could result in increased financial impact to covered entities.

***Comments on the Reporting Requirements***

- Reconciliation detail for payment of 340B rebates needs to be available via API for covered entities and associated partners (such as TPAs) from the IT platform
- For the IT platform that is utilized, we need to be able to have access to transaction reports to reconcile the submitted claims back to the transaction IDs. Originally, one of the IT platforms only allowed access to this report as a one time download available to the user who uploaded the claims. No additional access to this report to tie back claims between the covered entity and IT platform would be available.
- Overall, additional administrative burden will be placed on covered entities to reconcile reimbursement at the claim level across entity owned outpatient pharmacies since the MFP rebate being effectuated through one IT platform providing payment directly to the dispensing pharmacy vs. the 340B rebate being effectuated through another IT platform(s) and receiving a lump sum repayment for the entire covered entity.
- Administrative burden will be placed on covered entities to reconcile the 340B rebate lump sum across multiple cost centers/dispensing locations to have visibility into drug expense across different areas.

***Comments on the Rebates***

- UNC Health advocates for a standard approach to 340B credits based on the package level or unit level across all manufacturers.
- The term duplicate discounts needs to be defined to align with the 340B statute (Medicaid FFS only) and ensure that this is the only way a manufacturer can deny a claim on the grounds of a duplicate discounts.
- The 340B rebate should always be prioritized as the rebate given by a manufacturer over other industry rebates, such as those given to commercial payers.
- UNC Health advocates for this proposal to define the term diversion as a reason for rebate denials since this term could be applied broadly by manufacturers.
- As stated previously, this proposal could increase the use of audits by manufacturers, thereby increasing the administrative burden of the rebate model on covered entities. More oversight and guidance around the scope of manufacturer audits should be provided in the proposal.
- This proposal does not specifically address drugs that are not qualify for 340B per 340B policies but have a lower 340B price than the MFP. Manufacturers are likely to exclude all claims for that drug by a covered entity due to the covered entity having 340B eligibility, and not the individual claim. This could create a financial burden to the covered entity if these ineligible claims are not allowed to have a MPF rebate.

***Comments on the Data***

- Data is not specifically limited to retail claims only. Without that distinction, it would put covered entities at a higher administrative burden if mixed-use claims are included.
- There will be an increased administrative burden to covered entities without one standard IT platform, with one set of standard data elements required, and one standard process for reconciliation. Additionally, without this standardization, covered entities are likely to make mistakes due to the variability across manufacturers, and thereby increasing financial harm.

# EXHIBIT 13

NORTON HEALTHCARE
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September 8, 2025

**Submitted to *Federal eRulemaking Portal:* https://www.regulations.gov**

Thomas J. Engels
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

**RE: 340B Rebate Pilot Program (HHS Docket No. HRSA–2025–14619)**

Dear Administrator Engels:

Scott Memorial Hospital CAH151334, which participates in 340B, provides these comments on the Health Resources and Services Administration's (HRSA) Notice inviting drugmakers to replace upfront 340B discounts with backend rebates on the ten (10) drugs subject to Medicare Part D negotiated prices starting in 2026.[1]

Our hospital strongly opposes the 340B Rebate Pilot and urges HRSA to continue implementing 340B as an upfront discount. Rebates will increase 340B participation costs significantly, redirecting funds to manufacturers that would otherwise go to patient care. Not only is this contrary to 340B's intent, but HRSA has not provided a policy rationale explaining its decision to change decades of requiring 340B to operate as an upfront price discount.

340B hospitals are a vital health care resource for low-income populations, especially those that are uninsured or covered by public insurance, which typically reimburses at rates below the cost of care. In fact, 340B hospitals deliver seventy-seven percent (77%) of all hospital care for Medicaid patients and sixty-seven percent (67%) of all hospital uncompensated and unreimbursed care.[2] The 340B program was established to reduce operating costs for participating providers – which often operate on thin or negative margins – so they can stretch limited resources to maintain and improve care for patients. Any change to longstanding policy that would increase costs for the very providers that the 340B program is intended to support demands a strong and well-supported justification – yet the notice does not provide one.

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[1] Health Resources and Services Administration, 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program; Correction, 90 Fed. Reg. 38165 (Aug. 7, 2025).
[2] Allen Dobson et al., 340B DSH Hospitals Serve Higher Share of Patients with Low Incomes (Dobson DaVanzo Health Economics Consulting (Sept. 26, 2022), https://www.340bhealth.org/files/340B_and_Low_Income_Populations_Report_2022_FINAL.pdf

Manufacturers have proposed rebate models to gather data to allegedly allow them to improve 340B program integrity and to make it easier for them to meet their compliance obligations under the Inflation Reduction Act (IRA), neither of which justify a rebate model.[3] HRSA already conducts routine audits of covered entities, which are resulting in minimal findings, and manufacturers have not presented any data demonstrating systemic integrity issues. For the IRA, they assert that a rebate model, including hospital disclosure of data associated with 340B drugs, is needed to identify 340B drug claims. But this could be addressed through a government-led data collection approach that removed 340B claims from the IRA data submitted to manufacturers, thereby avoiding any risk of duplication between 340B and the Medicare refund without replacing upfront discounts with rebates or sharing patient claims data with manufacturers. This would be a much less disruptive alternative for meeting the IRA's 340B non-duplication requirement.

**A Rebate Model Would Increase Costs for 340B Hospitals and Divert Resources Away From Patient Care**

The Rebate Pilot would require 340B hospitals to purchase the ten (10) medications subject to the IRA at prices significantly higher than the 340B price (wholesale acquisition cost/WAC or other commercial price) and wait to receive a rebate representing the difference between the higher price and the 340B price. We will be essentially forced to float substantial funds to pharmaceutical manufacturers – tying up critical resources that would otherwise support patient care and essential operations.

After buying the drug at this higher price, it goes into our inventory until it is eventually dispensed to a 340B patient, which could take weeks or months. At that point, we would be required to gather and submit data required by the manufacturer. The timing from purchase to dispense to sending data will depend on the needs of our patients at any given time. The high financial outlay when purchasing these drugs creates a strong need for us to submit the data as soon as possible, most of which we have not previously had to collect and submit to manufacturers. This will require extra resources and staffing, further increasing the costs we would be already incurring because of floating revenue to profitable manufacturers. The delays are particularly concerning for physician-administered drugs covered under a medical benefit, which hospitals maintain separately from pharmacy claims due to different filing requirements.

Prior experience submitting data under manufacturers' restrictive contract pharmacy policies requiring hospital submission of data in connection with 340B claims enhances our concern about delays, as access to 340B pricing has been inconsistent at best, even when all data requirements were met. Manufacturers were not fully transparent about additional requirements and limitations under their individual policies, resulting in additional delays or lack of pricing altogether. These issues have been well-documented and submitted to HRSA.

The Rebate Pilot will result in significant and extensive costs to our hospital, which will reduce resources available for patient care. Some of the negative impacts we foresee include an undermining of our ability to deliver timely medication assistance and inability to fund programs

[3] 90 Fed. Reg. at 38165.

for uninsured patients as these funds may not be available to subsidize uncompensated care, support wraparound services, expand clinics, and make medicines affordable for uninsured and underinsured patients.

**HRSA Should Prohibit All Rebate Denials and Continue To Exclude Invoice Data From Permitted Data Collection List**

If HRSA goes forward with the Rebate Pilot against our recommendation, we urge HRSA to prohibit manufacturers from denying *any* rebates from 340B hospitals and prohibit collection of hospital invoice data for drug purchases. While it is helpful that HRSA explicitly bans manufacturers from denials pertaining to alleged Medicaid duplicate discounts and diversion, we remain concerned that manufacturers may deny claims for a host of reasons and will provide unintelligible or overly narrow reason codes, making it nearly impossible to challenge without taking the claim through the Administrative Dispute Resolution process. For example, manufacturers could assert that they already paid the rebate for a claim to another covered entity, but there would be no way for us to confirm the truth of that statement unless they shared the name of the entity, which could raise Health Insurance Portability and Accountability Act (HIPAA) issues. Similarly, they could assert that the claim did not comply with their restrictive contract pharmacy policies, but that denial would not be under HRSA's purview because HRSA is not legally tasked with enforcing manufacturer conditions, raising questions about how a covered entity could challenge that denial. Simply put, as manufacturers have statutory authority to audit covered entities after providing the 340B price, they should also not be permitted to deny claims prior to providing the 340B price.

Manufacturer rebate proposals have required hospitals to provide manufacturers with invoice data to prove 340B drugs were purchased at WAC and prior to the date of dispense. We strongly oppose that burdensome and unnecessary requirement and applaud HRSA for excluding it from the data request list in the Rebate Pilot. Providing such data would require retrieval and review of large, complex reports from multiple wholesaler portals containing data extraneous to the Rebate Pilot just to isolate the required information. With potentially hundreds of thousands of transactions across wholesaler and contract pharmacy relationships, this time-consuming process may need to be repeated daily, increasing the risk of errors and rebate denials. Redirecting staff to manage this task would divert critical resources from patient care. Moreover, this requirement is redundant, as hospitals would be purchasing the drugs subject to rebates through their 340B-designated wholesaler accounts and so would have auditable information to confirm the WAC purchase if there were questions or audits by manufacturers.

Thank you for considering our comments.

Sincerely,
Scott Memorial Hospital

Amanda Castle, PharmD
System Vice President Pharmacy Services
Scott Memorial Hospital Primary Contact