No. 25-2236

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,
Plaintiffs-Appellees,

v.

ROBERT F. KENNEDY, JR., *Secretary of the U.S. Department of Health and Human Services, et al.*,
Defendants-Appellants.

On Appeal from the United States District Court
for the District of Maine

PLAINTIFFS-APPELLEES' OPPOSITION TO DEFENDANTS-APPELLANTS' MOTION FOR STAY PENDING APPEAL AND ADMINISTRATIVE STAY

Karen L. Dunn
Dunn Isaacson Rhee LLP
401 9th Street, NW
Washington, DC 20004
(202) 240-2900
kdunn@dirllp.com

Melissa A. Hewey
Drummond Woodsum
Attorneys At Law
84 Marginal Way, Suite 600
Portland, ME 04101
(207) 253-0528
mhewey@dwmlaw.com

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There is no parent corporation, publicly held corporation, affiliated corporation, limited liability company, partnership, firm, joint venture, trust, or other entity, or any individual, owning 10% or more of the stock of the American Hospital Association, Maine Hospital Association, Nathan Littauer Hospital & Nursing Home, or Unity Medical Center; or having 10% or more ownership interest in any of the aforementioned entities.

St. Mary's Regional Medical Center is a 501(c)(3) nonprofit subsidiary of St. Mary's Health System, of which Covenant Health is the sole corporate member. There is no publicly traded company that owns 10% or more of the stock of any of the aforementioned entities.

Dallas County Medical Center is an Arkansas county entity. There is no publicly traded company that owns 10% or more of the stock of Dallas County Medical Center.

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PRELIMINARY STATEMENT

Over three decades ago, Congress created a drug pricing program that has become a financial lifeline for safety-net healthcare providers. Defendants recently put this lifeline, the "340B Program," in serious jeopardy with a hasty, ill-considered, and unlawful decision to fundamentally change how the Program has operated since its inception. As a result of that decision, hospitals across America that serve rural and other underserved communities now face enormous, unrecoverable costs and imminent disruptions to patient care. Recognizing Plaintiffs' irreparable harm and Defendants' multiple violations of the Administrative Procedure Act, the district court correctly preserved the status quo by enjoining Defendants' illegal actions. That preliminary injunction should remain in effect as the case is heard in full.

Earlier this fall, Defendants initiated a so-called "340B Rebate Model Pilot Program" ("Rebate Program") that would impose hundreds of millions of dollars in administrative costs on safety-net hospitals, and force them to pay significantly higher prices to drug companies starting on January 1, 2026. The Rebate Program reversed a 33-year old policy without explanation or any acknowledgment of the devastating consequences on rural and safety-net healthcare providers. Defendants did this despite receiving numerous public comments warning of the catastrophic effect those administrative and other costs would have on safety-net hospitals and the patients they serve. *See Ohio v. EPA*, 603 U.S. 279, 293-94 (2024) (agency

"ignored an important aspect of the problem" where "commenters posed this concern to EPA during the notice and comment period, [but] EPA offered no reasoned response" (cleaned up)).

Based on this textbook failure to follow the Administrative Procedure Act ("APA"), Plaintiffs sued and sought preliminary relief before the Rebate Program commenced on January 1. The district court granted Plaintiffs' motion, holding that Defendants' decision-making "has involved a rather threadbare administrative record that likely fails to consider and reasonably explain the impact of a rebate model on 340B hospitals, who rely on upfront price concessions to stretch few resources as far as possible to serve rural and poor communities." Add. 2; *see DHS v. Regents of the Univ. of Cal.*, 591 U.S. 1, 33 (2020) (agency reversing policy is "required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns"). The district court also found that, because Defendants conceded they "are still evaluating administrative costs," they "have not yet considered an important aspect of the problem," which the district court rightly concluded was "fatal." Add. 16; *see Michigan v. EPA*, 576 U.S. 743, 752-53 (2015) ("Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions") (emphasis in original).

The district court's decision was correct, and Defendants therefore have no real chance of success on appeal—let alone the "strong showing" they need to obtain a stay. Defendants are equally unable to prevail on the remaining factors considered for a stay, and have waived many of the arguments they now press because they failed to timely raise them to the district court. Accordingly, Defendants' request for a stay pending appeal should be denied.[1]

If all of this were not enough, Defendants seek to manufacture urgency when there is none. At best, the asserted "'emergency' is largely one of their own making." *Respect Me. PAC v. McKee*, 622 F.3d 13, 16 (1st Cir. 2010); *see N. Mariana Islands v. United States*, 686 F. Supp. 2d 7, 21 (D.D.C. 2009). Defendants have had several years to prepare for the Inflation Reduction Act, but they—not America's safety-net hospitals—waited until the last minute to institute a Rebate Program without complying with the APA's most basic substantive requirements. Moreover, as the district court correctly explained, "there is no apparent, actual urgency to the January

[1] After being denied intervention below and appealing that denial, four drug companies and their trade association now improperly seek to intervene here to support the government's appeal. Doc. 00118385287. These drug companies "may not obtain appellate review" of the preliminary injunction order "unless and until the denial of intervention is reversed." *Nuclear Regul. Comm'n v. Texas*, 145 S. Ct. 1762, 1774-75 (2025). Plaintiffs will oppose the motion to intervene in the ordinary course absent another schedule set by the Court.

1 start date." Dkt.[2] 96 at 3. Defendants now concede that drug companies "have alternate means to deduplicate discounts," Mot. 8, which is their purported justification for a January 1 start. And Defendants already approved one drug company to commence its program on April 1, 2026, meaning there is no real significance to January 1, anyway. *Id.* at 5. With no true urgency, no likelihood of success, and no harm to the government, this Court should deny Defendants' motion.

BACKGROUND

Since the 340B Program's inception in 1992, Pub. L. No. 102-585 § 602 (1992), Defendants have required participating drug companies to provide discounts on certain prescription drugs at the time of the sale, known as an upfront discount. *See* 42 U.S.C. § 256b(a)(1); 58 Fed. Reg. 27289, 27291-92 (May 7, 1993). Many 340B providers, or "covered entities," operate on thin (or negative) margins and cannot afford market prices for drugs without sacrificing patient care. Supplemental Addendum ("Supp. Add.") 15-16. 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).

Drug companies have repeatedly tried to institute a "rebate" model, under

[2] Citations to "Dkt." refer to *Am. Hosp. Ass'n v. Kennedy*, No. 2:25-cv-00600-LEW (D. Me.).

which safety-net providers would be forced to pay full market price, or wholesale acquisition cost ("WAC"), and then seek reimbursement after administering the drugs. Such a change would impose hundreds of millions, if not billions, of dollars of costs on covered entities—a reality that Defendants have never refuted. A rebate system would involve vast administrative costs to submit, track, recover, and potentially resolve disputes over rebates. It also would force 340B hospitals to essentially provide drug companies with interest-free loans while awaiting refunds due by law. *See* Supp. Add. 11, 13-16.

HRSA historically rejected drug companies' rebate proposals. Since 2024, for example, HRSA has litigated against multiple drug companies to stop them from unilaterally deploying rebate programs. *See Novartis Pharms. Corp. v. Kennedy*, No. 25-5177 (D.C. Cir. Aug. 1, 2025) (consolidated cases for appeal). During these cases, Defendants repeatedly noted the risks and costs of introducing rebate models to the 340B Program. 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 Health Care Sys, Inc. v. Kennedy*, No. 1:24-cv-03188 (D.D.C. Apr. 2, 2025).[3] In August 2025, Defendants noted that "[u]nlike discounts, rebates

[3] The presiding courts agreed, pointing to concerns 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

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. Defendants also explained that Congress "expected that the Secretary of HHS" would "use the mechanism [to administer the 340B program] that is the most effective and most efficient from the standpoint of each type of covered entity." *Id.* at 25 (quoting H.R. Rep. 102-384, pt. 2, at 16 (1992)).

At the same time Defendants were highlighting the risks of a rebate model in court, HRSA abruptly announced its Rebate Program on July 31, 2025, followed by a notice in the *Federal Register* ("Notice"). The Notice stated that Defendants would allow certain drug companies to mandate 340B rebate pricing for specific drugs, effective January 1, 2026. Add. 47-48. 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 previously objected to.

Defendants labeled their Rebate Program a "pilot," but it is a pilot in name only. Rather than starting in a more circumscribed fashion, as is customary for any true pilot program, it applies to *every* 340B provider in America—approximately 14,600 entities by Defendants' own estimates. Participation is *compulsory* for those covered entities; they are *required* to participate or lose their statutorily-owed

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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).

discounts. By contrast, drug companies have the *option* of applying to participate.

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. Add. 47-49. But the cursory Notice did not elaborate on why such a convoluted Rebate Program involving the transfer of hundreds of millions of dollars was needed. *Id.* HRSA did not consider or address 340B providers' longstanding operational reliance on upfront discounts, nor the costs that would result from a sudden shift to a rebate model. *Id.* Finally, the Notice did not consider any of the obvious alternatives to the proposed Rebate Program. *Id.*

The Notice solicited comments from the public, and Defendants received over 1,100 within a month. Commenters detailed the costs and burdens that the Rebate Program would impose—none of which were discussed in the Notice. *See, e.g.*, Dkt. 10-8 at 13-14; Dkt. 10-17 at 2-3; Dkt. 10-21 at 1-2. Specifically, commenters focused on the calamitous effects of cash-strapped covered entities spending hundreds of millions of dollars on administrative costs, as well as floating billions of dollars to the drug industry while waiting for their 340B discounts. *See, e.g.*, Dkt. 10-18 at 5-7; Dkt. 10-10 at 4-5; Dkt. 10-14 at 2-3. Commenters also flagged other operational

concerns and alternatives to the Rebate Program. *See, e.g.*, Dkt. 10-8 at 5-7; Dkt. 10-13 at 2; Dkt. 10-16 at 8; Dkt. 10-17 at 3-4. Defendants ignored all 1,100 comments and did not address the many problems the public raised.

Instead, Defendants barreled ahead with the Rebate Program. Between October 30 and November 14, 2025, HRSA approved rebate program applications privately submitted by nine drug companies for ten drugs. Mot. 5. All ten drugs are high-volume, high-cost brand-name drugs and will impose, in HRSA's words, "significantly higher up-front costs for covered entities," Dkt. 41-1 at 19, *J&J*, No. 1:24-cv-03188, and "cause unprecedented disruption to the [340B] program," Dkt. 35-1 at 20, *Eli Lilly & Co. v. Kennedy*, No. 1:24-cv-03220 (D.D.C. Mar. 17, 2025).

Plaintiffs filed suit on December 1, 2025, alleging numerous failures to comply with the APA. Dkt. 1. Defendants, in response, produced no contemporaneous records demonstrating that their "agency action [was] reasonable and reasonably explained," *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021), or a "product of reasoned decisionmaking." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 52 (1983).

Instead, weeks after they made their approval decisions, Defendants submitted a declaration from Chantelle Britton prepared solely for this litigation. Add. 25-40. The Britton Declaration offered some *post-hoc* rationalizations for the Rebate Program but did not identify any contemporaneous documents that shared those

rationalizations. Furthermore, Defendants made several fatal concessions in the Britton Declaration, most notably that they did not adequately assess the costs of the Rebate Program *prior to* approving the drug companies' applications and that Defendants were still "currently examining the comments alleging an under-estimation of administrative costs." Add. 34 ¶ 35.

On December 29, the district court granted Plaintiffs' preliminary injunction motion. Add. 24. The district court found Plaintiffs' showing, particularly on likelihood of success and irreparable injury, to "tilt[ ] the board decisively in Plaintiffs' direction." Add. 8. In assessing Plaintiffs' likelihood of success, the court found that the "anemic" administrative record alone "support[ed] a conclusion that Plaintiffs have made a strong showing of likelihood of success." Add. 8-10.

Even after assessing both the Britton Declaration and belatedly filed documentation showing correspondence between HRSA and some of the drug companies, the district court found Defendants' failure to address reliance interests and costs "fatal" to Defendants' arguments. Add. 12-18. The court also found that the harms Plaintiffs would incur from the Rebate Program to be both irreparable and concrete. Add. 19-20. Finally, in balancing the equities, the court noted that its preliminary injunction "would preserve the status quo and preserve the reach of 340B entities to continue serving the public's significant interest in receiving critical medical services." Add. 21.

ARGUMENT

Defendants elide the proper standard for a stay motion, never acknowledging they must make a "strong showing" they are likely to succeed on appeal. Mot. 8. But "[a]s the party seeking a stay pending appeal, the government bears the burden of justifying the extraordinary relief it requests." *New York v. Kennedy*, 155 F.4th 67, 72 (1st Cir. 2025); *see Nken v. Holder*, 556 U.S. 418, 433-34 (2009). The relevant factors are: (1) whether the government has made a strong showing it is likely to succeed on the merits of its appeal; (2) whether the government has shown it will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure other interested parties; and (4) where the public interest lies. *New York*, 155 F.4th at 72. Defendants cannot satisfy any of these factors.

I. Defendants Cannot Make A "Strong Showing" They Are Likely To Succeed On The Merits.

A. The District Court Correctly Held That Defendants Ignored Costs And Reliance Interests.

The district court correctly concluded that Defendants failed to appropriately consider the costs that the Rebate Program would inflict on 340B hospitals and those hospitals' longstanding reliance interests in the upfront discount model. Defendants have not made—and cannot make—a "strong showing" to the contrary.

Costs. Although Defendants focus predominantly on arguing (wrongly) that the district court refused to consider the Britton Declaration, the district court's

decision with respect to *administrative costs* turned on the Britton Declaration itself. There, the declaration conceded that Defendants are still examining those costs even after they approved the drug companies' applications to the Rebate Program. Add. 34 ¶ 35. Given that concession, the district court correctly held that the "failure to consider administrative costs before approving the manufacturers' applications under the Rebate Program is fatal under the APA." Add. 17.

Defendants do not dispute that they were required to consider costs and weigh them against any benefits of the Rebate Program. Instead, they now seek to escape this fatal concession by arguing (for the first time) that they are permitted to proceed on "two tracks" with respect to analyzing costs: they can move forward with their Rebate Program while continuing to study the costs of the program to satisfy their separate obligations under the Paperwork Reduction Act (PRA). Mot. 21 (citing 44 U.S.C. § 3507(j)(1)). Defendants never made this argument before the district court issued its order and therefore have waived it. *E.g.*, *United States v. Tanco-Pizarro*, 892 F.3d 472, 479 (1st Cir. 2018); *Iverson v. City of Boston*, 452 F.3d 94, 102 (1st Cir. 2006). Even so, this new contention ignores the APA violation that is inherent in the Britton Declaration's concession: Defendants still have no idea whether the Rebate Program will require "too much wasteful expenditure devoted to one problem[, which] may well mean considerably fewer resources available to deal effectively with other (perhaps more serious) problems." *Michigan*, 576 U.S. at 753

(citation omitted). Likewise, Defendants have never articulated how any purported benefits of the Rebate Program outweigh the costs to covered entities, which Defendants concede would amount to hundreds of millions next year *at a minimum*. *See infra* p. 20. The most Defendants offer is the "bald assertion that the benefits of the Rebate Program outweigh any negative impact." Add. 17. But as the district court correctly held, Defendants' "naked claim that we should simply take their word for it," Add. 17-18—or what their motion now tries to dress up as a "predictive judgment," Mot. 22—is not sufficient under the APA.

Defendants' failure to complete their analysis of administrative costs *before* approving the drug companies' applications is especially problematic because stakeholders raised concerns about administrative costs in their comments during *two* comment periods. Commenters provided significant amounts of information about administrative costs, yet the agency *never* responded to them or factored them into its analysis prior to approving the drug companies' applications. Quite the contrary, Director Britton expressly admitted that "the agency is still reviewing public 'comments alleging an under-estimation of administrative costs…and will [later] address those concerns.'" Add. 34 ¶ 35. Making a final decision before considering comments about such an important aspect of the problem is a straightforward APA violation. *See Ohio*, 603 U.S. at 293-94.

To use one example, Defendants calculated that covered entities "would need

to expend, on average, two hours per week" to comply with the new burdens of the Rebate Program. Mot. 22. But numerous commenters explained that providers would need to hire or reassign *full-time employees* to comply with the Rebate Program. *E.g.*, Dkt. 10-21 at 2; Supp. Add. 21. Yet Defendants nowhere addressed how they arrived at their estimate or how it could be correct in light of the data they received through comments.[4] This failure illustrates why the district court correctly held that Defendants failed to consider an important aspect of the problem when Director Britton conceded Defendants are *still* reviewing administrative costs and multiple comments explain why the agency's two-hour estimate (and other cost estimations) was wrong.[5]

Reliance Interests. Defendants also do not dispute that they were required to consider 340B hospitals' reliance interests. But their motion devotes almost no

[4] Defendants at one point argue that Plaintiffs "fail to explain" that they "will need to expend more time to claim rebates." Mot. 22. Despite receiving numerous comments and declarations in this case, Defendants still cannot bring themselves to admit that hospitals will need to hire full-time employees to submit claims data, track rebates, potentially dispute denials, and do all the new work necessitated by this fundamental transformation of the 340B Program. Perhaps Defendants will have a better understanding of why full-time employees are needed when they complete their analysis of costs. But for now, this willful blindness toward the true scope of administrative costs impermissibly contradicts the evidence in the administrative record. *E.g.*, *City of Kansas City, Mo. v. HUD*, 923 F.2d 188, 194 (D.C. Cir. 1991).

[5] Defendants repeatedly insist that the data they are allowing drug companies to demand is duplicative of data covered entities already submit. Mot. 14, 20. But that is untrue, as numerous commenters explained. *See, e.g.*, Dkt. 10-18 at 5; Supp. Add. 25-26. Defendants still have not considered those comments, either.

attention to the issue, even though this was one of the district court's central holdings.[6] At most, much like they did below, they point to a single sentence in the Notice acknowledging that the Rebate Program would fundamentally change the 340B Program. Add. 48. But as the district court correctly held, "[n]oting a change in a program's operation is not the same as recognizing that the change will impact 340B entities in detrimental ways[,]" nor does it demonstrate that Defendants "weighed any reliance interest against the competing de-duplication policy concern or the proposed de-duplication approach favored by the participating manufacturers." Add. 14.

In fact, even the *post-hoc* assertions that Defendants seek to rely on do not cure these failings. Based on stray statements in the Britton Declaration, Defendants assert in their motion that they designed the Rebate Program to account for reliance interests, including by limiting the Rebate Program to ten drugs and providing lead time before the program went into effect. Mot. 14. But even if it were true that these features were aimed at protecting reliance interests and not *post-hoc* rationalizations, they still do not demonstrate that Defendants "determine[d] whether [hospitals' reliance interests] were significant, and weigh[ed] any such

[6] Defendants included a subsection entitled "HHS properly considered plaintiffs' reliance interests and compliance burdens," but do not discuss the idea of reliance interests therein. Mot. 20-24.

interests against competing policy concerns." *Regents*, 591 U.S. at 33. They also certainly do not amount to the "more detailed justification" required when an agency changes position "when its prior policy has engendered serious reliance interests." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

Indeed, those minimal design features "do[] not account for the broad scope of financial and non-financial interests" that hospitals developed when relying on an upfront discount model for 30-plus years, "[n]or do[they] have any bearing on whether [Defendants] considered those myriad interests" before approving the drug companies' applications, "which [they were] required to do under the APA." *Am. Pub. Health Ass'n v. NIH*, 145 F.4th 39, 54 (1st Cir. 2025). Thus, *with or without* the Britton Declaration, the district court correctly held that Defendants failed to properly account for 340B hospitals' decades-long reliance interests.[7]

[7] At one point, Defendants insist that they were under no obligation to explain their decisions because they were purportedly conducting informal adjudications. *See* Mot. 15-16. Remarkably, Defendants argued the opposite below. *See* Supp. Add. 50; Preliminary Injunction Hearing Tr. 31:22-32:16 (government counsel arguing that "even though agencies have to provide some explanation for their decisions, it doesn't need to be elaborate"). Thus, this argument was "not squarely and timely raised in the trial court [and] cannot be pursued for the first time on appeal." *Iverson*, 452 F.3d at 102. More importantly, it is wrong. The APA's substantive requirements apply to all reviewable agency action, including informal adjudications. *E.g.*, *Harrington v. Chao*, 280 F.3d 50, 58-59 (1st Cir. 2002) ("the requirement of adequate explanation is an inevitable consequence of applying the APA's arbitrary and capricious standard" even in cases that involve neither formal rulemaking nor adjudications); *W. Coal Traffic League v. Surface Transp. Bd.*, 998 F.3d 945, 954 (D.C. Cir. 2021) (similar).

B. The District Court Appropriately Discounted The Britton Declaration.

As discussed *supra*, the district court did not need to discount the Britton Declaration to conclude that Plaintiffs are likely to succeed on the merits of their APA challenge. Nevertheless, given the paucity of the existing administrative record, much of Defendants' motion is dedicated to rehabilitating that barren record by arguing about the Britton Declaration. Mot. 15-24. Although unnecessary to the district court's ultimate holding, the court appropriately discounted that declaration as a *post-hoc* rationalization of Defendants' actions.

The district court would have been well within its discretion to completely disregard the Britton Declaration. As the Supreme Court recently held, *post hoc* "litigation affidavits" and other "belated justifications" are prohibited in APA proceedings because considering them would undermine "important values of

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Defendants also argue for the first time that "experimental programs require less justification than permanent changes." Mot. 12; *contra* Tr. 37:12-39:8 (district court asking about the relevance of Defendants' designation of the Rebate Program as a "pilot" and defense counsel omitting any argument for a lower standard for APA review). Even setting aside that Defendants have waived this argument, the sole half-century old case they rely on is inapposite. In that case, the court expressly noted that there was "no record." *Aguayo v. Richardson*, 473 F.2d 1090, 1094–95 (2d Cir. 1973). Here, by contrast, there is a robust record of commenters raising important problems, including reliance interests and costs to 340B hospitals, that the agency ignored. Assigning the name "pilot program" to an agency action—especially where it is undeserving of that monicker, *see supra* p. 6—does not excuse an agency from complying with the basic APA "rules that guide [a court's] analysis," including that it must address comments identifying an important aspect of the problem and provide a satisfactory explanation for its actions. *Ohio*, 603 U.S. at 292-93.

administrative law." *Regents,* 591 U.S. at 22-23; *id.* at 23 (citing *Citizens to Pres. Overton Park, Inc. v. Volpe,* 401 U.S. 402, 419 (1971), for its "rejecting 'litigation affidavits' from agency officials as 'merely '*post hoc*' rationalizations'"). The Court's *Regents* decision postdates every case from the Supreme Court or this Circuit that Defendants cite to justify their reliance on the Britton Declaration.

In any event, the district court did not fully discard the declaration. Defendants wrongly claim that the district court "refus[ed] to consider [the Britton] declaration," Mot. 16, but the district court was careful to explain that "[t]o the extent that this tatty administrative record is ambiguous, I consider the Britton Declaration for clarity, but because the record is mostly silent on salient considerations that would guide any rational policy-making process, Director Britton's representations are, for the most part, of no use." Add. 11. In other words, the district court *did* consider the Britton Declaration but found it of little value due to the lack of evidence elsewhere in the record. This skeptical approach follows exactly the way this Court instructed courts to consider litigation affidavits—to illuminate an existing administrative record but not as a replacement for a non-existent or threadbare administrative record. *See Sierra Club v. Marsh*, 976 F.2d 763, 774 (1st Cir. 1992) (relying on a litigation affidavit only where "the affidavits [did] not contain any 'facts' about the proposed project that are not also included in the EIS and administrative record."); *see also California v. U.S. Dep't of Educ.*, 132 F.4th 92, 99 (1st Cir. 2025) (rejecting

belated agency affidavit intended to "provide further specificity" where "that supposed specificity is nowhere to be found" in the record).[8]

Viewing the Britton Declaration with an appropriately critical eye, the district court's conclusion that Defendants ignored both costs to 340B hospitals and their reliance interests is unassailable. *First*, the district court correctly found that the administrative record 1) was "silent on the cost of floating the full price of covered drugs until 340B entities receive their rebate," and 2) did not address "non-monetary costs, to 340B entities, including the impact these additional prices might have on [hospitals'] long-term viability." Add. 17. *Second*, as noted, the district court correctly observed that Defendants provided no real discussion of reliance interests in the administrative record. Add. 15. Thus, absent any discussion in the contemporaneous record about either of these critical issues, there was nothing for

[8] Defendants cannot avoid preliminary relief by protesting that they may be able to offer the new explanations in the Britton Declaration on remand after summary judgment is granted against them. *See* Mot. 18. *First*, adopting Defendants' argument that an agency can escape preliminary relief whenever it could possibly redo its action in compliance with the APA would impermissibly render the APA's preliminary relief provision, 5 U.S.C. § 705, a nullity. *Second*, it would undermine the important values that the Supreme Court identified in *Regents* when rejecting the use of *post-hoc* litigation affidavits, including promoting agency accountability and public confidence that the reasoning in those affidavits is not just in response to litigation. 591 U.S. at 22-23. *Third*, Defendants' assertion that they would reach the same conclusions on remand as those in the Britton Declaration, even as they admit they are *still* considering costs, Add. 34, only further proves that Defendants unlawfully sought a predetermined result. *See* Dkt. 1, Count V.

the Britton Declaration to illuminate.

In sum, Defendants violated the APA and are unlikely to succeed on appeal.

II. Defendants Face No Concrete Harm Absent A Stay.

Defendants' failure to make a strong showing on the merits is fatal. *Nken*, 556 U.S. at 427. Regardless, Defendants have also made no showing whatsoever that they will sustain irreparable injury.

The only purported injuries Defendants obliquely reference are a "disruption to the rollout of the Negotiation Program" and *drug companies'* preparations for the Rebate program. Mot. 8-10.[9] Defendants cite no case for the proposition that harm to a third-party can serve as harm to the government for purposes of the stay analysis. But more fundamentally, the district court's preliminary injunction has no effect on negotiated Maximum Fair Prices ("MFPs") slated to take effect on January 1 under the Inflation Reduction Act. Defendants do not explain why or even how that program may be "disrupted," especially because they now concede that deduplication can be accomplished without the Rebate Program. Mot. 8, 13. This was already clear because one drug company, Novartis, was not scheduled by Defendants to start its Rebate Program until April 1, but Defendants' concession

[9] Neither of these arguments was advanced below, so they too are waived. *Supra* p. 11. But if the Court considers them, they serve as concessions Defendants themselves face no harm.

reinforces that they face no immediate irreparable harm. Mot. 5.

III. The Equities Tilt Decisively In Favor Of Plaintiffs.

The final two factors also favor Plaintiffs, who will be irreparably harmed if a stay is issued and whose interests align with the public interest. *See Nken*, 556 U.S. at 433-34.

All parties agree the Rebate Program will impose hundreds of millions of dollars in compliance costs on 340B providers. Defendants concede these administrative costs alone will be at least $200 million, and Plaintiffs estimate the costs will exceed $400 million—a figure the district court accepted and that remains unrefuted. Add. 16, 20; Supp. Add. 13. Individual Plaintiffs filed declarations explaining how those costs will materialize, from additional hires to increased vendor fees. *E.g.*, Supp. Add. 75, 81, 87, 93. "[W]hile the loss of money is not typically considered irreparable harm, that changes if the funds 'cannot be recouped' and are thus 'irrevocably expended.'" *NIH v. Am. Pub. Health Ass'n*, 145 S. Ct. 2658, 2660 (2025) (citation omitted). Plaintiffs also will be harmed by floating to drug companies the WAC of 340B medications, even for short periods of time.[10] Together, the staggering compliance costs and fronting the full price of 340B drugs will cause

[10] 340B providers often operate on razor-thin margins. For example, the average hospital in Maine has less than 11 days of cash on hand. Supp Add. 2-3. Defendants' argument that a ten-day rebate window cannot constitute harm therefore ignores reality and the record. Mot. 10.

harmful real-world effects. Plaintiffs will be forced to delay or cut healthcare services so they can find enough resources to comply with the Rebate Program. Dkt. 3 at 18-19.

Similarly, the district court recognized that the "downstream effect[s]" of the Rebate Program would cause hospitals to "cut back services." Add. 20. This, too, contravenes the public interest. *Rio Grande Cmty. Health Ctr., Inc. v. Rullan*, 397 F.3d 56, 77 (1st Cir. 2005) (affirming preliminary injunction was in the public interest because "any shut down of [the clinic] would adversely affect hundreds of Medicaid patients"); *see Mass. Ass'n of Older Ams. v. Sharp*, 700 F.2d 749, 753-54 (1st Cir. 1983); Supp. Add. 14-16. The concrete, severe harms facing Plaintiffs, their patients, and the public interest stand in contrast to the purported harms to drug companies (not the government) posited in Defendants' Motion.

CONCLUSION

This Court should deny Defendants' motion for a stay pending appeal.

Dated: December 31, 2025

Respectfully submitted,

/s/ Karen L. Dunn

Karen L. Dunn (Bar No. 1187151)
Dunn Isaacson Rhee LLP
401 9th Street, NW
Washington, DC 20004
(202) 240-2900
kdunn@dirllp.com

Melissa A. Hewey (Bar No. 40774)
Drummond Woodsum Attorneys At Law
84 Marginal Way, Suite 600
Portland, ME 04101
(207) 253-0528
mhewey@dwmlaw.com

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 27(d)(2)(A) because it contains 5,195 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word in Times New Roman 14-point font, a proportionally spaced typeface.

/s/ Karen L. Dunn

Karen L. Dunn

SUPPLEMENTAL ADDENDUM

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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, ET AL., Defendants.	Case No. **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

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, ET AL., Defendants.	Case No. **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

EXHIBIT 23

September 8, 2025

Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program (HHS-2025-14619)

Dear Director Britton:

MCR Health is a private, not-for-profit healthcare system and Federally Qualified Health Center. MCR Health provides Family Practice, Internal Medicine, OB/GYN, Behavioral Health, Vision, Dental and many other services, and proudly serves the Manatee, Sarasota, and Desoto counties.

MCR Health's services are provided at 28 Health Care Centers (which include 3 mobile units), 13 pharmacies, and 8 Administrative sites.

As you know, Community Health Centers (CHC) are the best, most innovative, and resilient part of our nation's health system. For sixty years, CHCs have provided high-quality, comprehensive, affordable primary and preventive care. In addition to medical services, CHCs provide integrated dental, behavioral health, pharmacy, vision, and other health services to America's most vulnerable, medically underserved communities in rural, urban, suburban, frontier, mountain, and island communities. Today, the health center workforce of 326,000 serves nearly 34 million people at over 17,000 locations, ensuring patients receive the care they need and pay what they can based on a sliding fee scale.[1]

MCR Health maintains its role as a regional voice for CHCs and believes high-quality primary health care is essential in creating healthy communities and preventing chronic conditions. The collective mission and mandate of MCR Health and the 1,512 CHCs nationwide are to close the primary care gap and provide high-quality, cost-effective primary and preventive medical care to communities across this country. When we improve patients' health, we help people to go back to work, and we lower health care costs,[2] and we support local economies.[3]

I. MCR Health Strongly Urges HRSA To Exempt Community Health Centers from the 340B Rebate Model Pilot Program.

[1] 2025 UDA Data, HRSA. (hrsa.gov)
[2] https://www.nachc.org/wp-content/uploads/2025/01/PolicyPapers_NationalValueImpact_FINAL_Jan2025.pdf
[3] Ibid.

101 Riverfront Blvd., Suite 710, Bradenton, FL 34205 ● 941-776-4000 ● mcr.health

The proposed 340B Rebate Model Pilot Program is a direct threat to the core mission of Community Health Centers and a significant departure from the original purpose of the 340B Drug Pricing Program. For over three decades, the 340B program has allowed health centers to purchase outpatient medications at significantly reduced costs, enabling them to provide affordable and sometimes free medications to millions of low-income and uninsured patients. As congressional intent made clear, the program was created to help safety-net providers "stretch scarce Federal resources as far as possible." The proposed rebate model undermines this by placing an immense financial burden on health centers.

By requiring health centers to purchase medications at full price and wait for a rebate, this model would cause significant financial turmoil and directly impact CHCs ability to serve the 34 million patients who rely on us. The National Association for Community Health Centers (NACHC) data indicates that without discounted or free medications, a substantial portion of CHC patients—up to 3 million or more—would lose access to essential treatments.[4] These patients often have chronic conditions like diabetes, heart disease, and behavioral health needs. They depend on the essential drugs included in the rebate pilot more than patients with any other conditions.

A change of this nature will have an immediate and direct impact on patients at the pharmacy counter. It would limit the range and volume of drugs health centers can afford to stock, directly contradicting the program's goal of increasing access to affordable medications. Since 90% of health center patients are at or below 200% of the federal poverty level, they rely on discounted medications from their local health center.[5] **We strongly urge HRSA to exempt Community Health Centers from any rebate model to protect the financial stability of safety-net providers and ensure continued access to care for the most vulnerable patients.**

A. MCR Health Harbors Significant Concerns That a Rebate Model Would Create Administrative Complexities and Financial Challenges for Health Centers.

Under the proposed 340B Rebate Model Pilot, health centers would be required to purchase drugs at full retail price, also known as Wholesale Acquisition Cost (WAC). This departure from over 30 years of precedent would drastically impact health centers' ability to purchase drugs due to the uncertainty of waiting for a manufacturer to approve a rebate, thereby constraining a health center's cash flow. Health centers will have to wait to receive their rebate payment *after* providing medications to their patients. **MCR Health appreciates HRSA's requirement for a 10-day timeframe for rebate payments; however, we have concerns about the lack of details regarding enforcement if manufacturers fail to meet this requirement.** Recent data suggests that the median cash-on-hand for CHCs is 100 days, and a quarter of CHCs have -4% operating margins. MCR Health anticipates additional financial challenges for health centers due to future changes in Medicaid eligibility and Marketplace insurance, which will likely increase uncompensated care costs. Health centers utilize the revenue generated from the 340B Program to provide affordable healthcare services and medications to uninsured and underinsured patients. If health centers are required to participate in the 340B Rebate Model Pilot Program, this will

[4] https://www.hcadvocacy.org/wp-content/uploads/2023/02/NACHC-340B-Report-Summary-June-2022.pdf
[5] Ibid.

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significantly impact their "scarce federal resources" and ability to fulfill the health center mission to serve all patients, regardless of their ability to pay. Health centers will have to make difficult decisions on how to utilize their limited financial resources, which could result in cutting essential health services, reducing operating hours, or discontinuing services that support patients' healthy outcomes.

Additionally, a rebate model would create confusion with its interaction and impact on a health center's ability to offer sliding fee discounts at the point of purchase. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of the project.[6] In alignment with their mission, CHCs often implement flat discounts or sliding fee discounts to make prescription drugs more affordable for low-income individuals. A health center can adjust the cost of health care services, including medications, based on a patient's income and family size. **The proposed 340B Rebate Model Pilot would have a direct impact on health centers' ability to offer patients steeply discounted medications at the point of sale, resulting from purchasing the full WAC pricing upfront. Health centers' pharmacies, entity-owned and contract pharmacies, will not have access to the 340B price at the time the patient needs the medication.** This will create a very unpredictable process for determining the level of discount and pricing for a patient's medication, as the 340B price will no longer be reflected in the pharmacy software from the wholesaler's price catalog, since initial purchase prices will be at WAC.

While rebates are expected to arrive within 10 days, there may be delays in receiving the full rebate, such as denials, which could create financial strain on health centers. MCR Health appreciates HRSA's requirement for a 10-day timeframe for rebate payments; however, we have concerns about the lack of details regarding enforcement if manufacturers fail to meet this requirement. **CHCs are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead them to exceed their credit limits with wholesalers, halting their ability to order medications until payments are submitted.** Complicatedly, the rebate amount may not match the initial discount offered to the patient, creating unpredictable financial losses. CHCs must guess the rebate amount and could potentially undercharge or overcharge patients due to confusion.

Furthermore, if the rebate is denied, the health center takes a net loss on the transaction. The proposed 340B Rebate Model Pilot also presents challenges for compliance with 340B actual acquisition cost billing in fee-for-service Medicaid, which may lead to increased Medicaid costs. Both are because pharmacy software will not have access to the 340B price, which is necessary for accurate drug pricing.

HRSA should exempt health centers from the 340B Rebate Model Pilot because health centers will incur additional workforce and IT costs to maintain compliance with multiple manufacturer rebate requirements. Similar to navigating manufacturers' existing contract pharmacy restrictions, health centers will need to hire or reassign existing staff to untangle the mentioned complexities related to varying data submission requirements, timelines, and systems.

[6] HRSA FAQ

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Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, health centers will face an increased administrative burden in terms of monitoring rebate claims and payments. The lack of standardization and varying requirements from each manufacturer will likely force health centers to use multiple systems to manage and report the same data, thereby increasing both costs and operational burdens. Health centers will need to invest in IT infrastructure upgrades and reassign staff to manage this new complexity, including reconciling payments and initiating dispute processes for denied rebates. MCR Health urges HRSA to require uniformity among eligible manufacturers to mitigate potential administrative and financial burdens associated with receiving timely and appropriate 340B rebates.

The proposed 340B Rebate Model Pilot Program is not only a financial threat to health centers but also a duplicative and unnecessary administrative burden. In an attempt to address manufacturers' "concerns" about duplicate discounts, the Pilot Program would force health centers to divert even more scarce resources away from patient care. Health centers have already absorbed significant administrative and technology costs over the past four years to comply with manufacturers' existing contract pharmacy restrictions by submitting data to 340B ESP.

Adding additional requirements under the proposed pilot would not only be a double burden but would fundamentally weaken the ability of health centers to provide affordable medications. This would have a direct impact on the most underserved CHC patients who rely on the up-front 340B discount to afford their treatments. Rather than serving as a solution, the pilot program would be a new barrier, further limiting the availability of affordable medications for patients with chronic conditions. **For this reason, MCR Health urges HRSA to deny manufacturers' requests to participate in the 340B Rebate Model Pilot Program if they have existing contract pharmacy restrictions**.

B. Operating as National Models of Compliance, Health Centers are Subject to a Robust, Layered Oversight Structure That Ensures Both Transparency and Unwavering Program Integrity.

Health centers already operate under a comprehensive regulatory framework, established through the Health Center Program and the 340B statute, to make medications affordable for patients. In alignment with Section 330 of the Public Health Service Act, we utilize a sliding fee discount that adjusts costs based on a patient's income and household size, ensuring that no one is denied services due to an inability to pay. Health centers must also establish systems for eligibility determination and offer full discounts to individuals at or below 100% of the Federal Poverty Level (FPL). These services would not be possible without the savings generated from the 340B program.

Health centers pride themselves on maintaining compliance with both the Health Center Program requirements and the 340B program, adhering to rigorous oversight and compliance processes. Not only do they participate in regular **Operational Site Visits (OSVs)** to verify Health Center Program compliance, but they also follow strict 340B compliance protocols, including internal audits, training, and the use of external oversight. This demonstrates a proven ability to manage 340B with integrity and accountability. In addition to implementing internal best practices, such

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as regular audits and staff training, health centers participating in the 340B program are required to report 340B-related information annually through the **Uniform Data System (UDS)**. This includes data on 340B-purchased drugs, associated costs and revenues, as well as detailed information about the patients served by the program. These reporting requirements provide a clear and consistent picture of how 340B savings are utilized to expand access and improve patient outcomes, consistently demonstrating health centers' exemplary stewardship of the program.

Given the compliance infrastructure and strict statutory requirements already in place for health centers, implementing a rebate model would cause disproportionate harm to health centers and the patients they serve. The administrative, financial, and operational burdens from such a model would threaten the stability of the safety-net providers that the 340B program was designed to support. CHCs are not the source of misuse in the 340B program; rather, they are national models of compliance.

CHCs are required to provide sliding fee discounts for patients under 200% of the federal poverty guidelines. Currently, CHCs routinely provide discounts to uninsured and underinsured patients, but a rebate model would make this operationally impossible because they rely on wholesale price files to determine the acquisition cost of the drug to calculate a discounted price. In a rebate model, the price file will give the WAC price, making the price unattainable for the patient. If health centers are included in this pilot, it will be extremely difficult to offer the included medications at a discount. For these reasons, **MCR Health encourages HRSA to exempt all CHCs from this pilot program.**

II. MCR Health Urges HRSA to Exempt Health Centers from the 340B Rebate Model Pilot to Protect the Most Vulnerable Patients' Access to Life-Saving Medications.

The drugs included in the proposed 2026 rebate model are primarily used to manage chronic conditions prevalent in primary care settings, meaning health center patients will be disproportionately affected. CHCs serve a patient population with a **higher burden of chronic conditions** compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity. This patient population relies on affordable medications to manage these long-term conditions. Displayed below please find the distribution by drug of the **10,516 annual patient visits** to our entity-owned pharmacies that will be impacted. The matrix below does not account for contract pharmacy implications.

Eliquis	Enbrel	Entresto	Farxiga	Imbruvica
1176	44	180	2384	0
Januvia	Jardiance	Novolog	Stelara	Xarelto
1952	4445	172	0	163

MCR Health is deeply concerned that the implementation of a rebate model would cause health center patients to lose access to essential, life-sustaining therapies. For instance, **direct oral anticoagulants (DOACs)** like Xarelto® and Eliquis® are vital for patients with deep-vein thrombosis, pulmonary embolism, and atrial fibrillation. For many of our patients, there are minimal and often less safe alternatives. This is not an optional therapy but a critical tool for

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survival, as one study showed that discontinuing these drugs leads to a statistically significant increase in the risk of stroke, heart attack, and death.[7]

Similarly, the impact on patients requiring **SGLT2 inhibitors**, such as Farxiga® and Jardiance®, would be severe. These drugs are a mainstay of primary care for conditions like Type 2 Diabetes, chronic kidney disease, and heart failure—all of which are highly prevalent among our patients. Research has found that even a 30-day withdrawal of these inhibitors increases the annualized risk of cardiovascular death or heart failure hospitalization.[8] By making these drugs unaffordable, the rebate model would effectively deny our patients access to the most effective therapies for managing their chronic illnesses, leading to a predictable increase in preventable hospitalizations.

The impact on **insulin access** is particularly alarming and directly conflicts with federal requirements. With over 3 million Americans depending on health centers for essential diabetes care,[9] the affordability of insulin is a matter of life and death. Furthermore, **Executive Order #14273 conditions future Section 330(e) funds on health centers providing access to discounted insulin** to low-income patients. There is currently no operational method to provide these discounted medications in a retrospective rebate model. In the proposed model, the wholesaler price file would reflect the full Wholesale Acquisition Cost (WAC) price instead of the discounted 340B price. This makes the price unattainable for the patient and **precludes health centers from fulfilling their legal obligation to offer the required discount at the point of care**.

Imposing a rebate model on health centers would only weaken the safety-net providers that 34 million Americans rely on for health care. CHCs are required to provide sliding fee discounts to patients with incomes at or below 200% of the federal poverty guidelines. The same patients who need access to discounted medical services are also the ones who depend on health centers to provide access to affordable medications. Without the up-front 340B discount, this would become operationally impossible for the drugs included in the pilot. **This model would create a new and significant barrier, rather than a solution, for our most vulnerable patients, especially those who are uninsured and have limited options for affordable care.**

III. Concerns Regarding the Pilot Program's Design and Scope

A. MCR Health requests additional guidance from HRSA and CMS on the intersection of the IRA and 340B Rebate Model Pilot Program.

While MCR Health acknowledges the pilot's intent to establish a fair and transparent process, we are deeply concerned that its proposed approach for addressing Inflation Reduction Act (IRA) requirements will create significant administrative, financial, and operational burdens for health centers. The IRA is a statutory requirement, and its provisions are not suggestions. HRSA must

[7] Cools F, et al. Risks associated with discontinuation of oral anticoagulation in newly diagnosed patients with atrial fibrillation: Results from the GARFIELD-AF Registry. J Thromb Haemost. 2021 Sep;19(9):2322-2334. doi: 10.1111/jth.15415. Epub 2021 Jul 23. PMID: 34060704; PMCID: PMC8390436.
[8] Packer, M., et al. (2024). Blinded Withdrawal of Long-Term Randomized Treatment with Empagliflozin or Placebo in Patients with Heart Failure. Circulation. https://www.ahajournals.org/doi/pdf/10.1161/circulationaha.123.065748
[9] 2025 UDA Data, HRSA (hrsa.gov)

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provide clear guidance on how its pilot will work with these existing mandates. However, the pilot's guidance on Medicare duplicate discounts fails to align with and, in fact, appears to contradict the clear statutory language of **Section 1193(d)** of the IRA.

The IRA provides two distinct nonduplication scenarios, explicitly directing manufacturers to provide the lower of the two prices:

1. When the 340B ceiling price is lower than the MFP, manufacturers are required to provide the 340B price.
2. When the MFP is lower than the 340B ceiling price, manufacturers are required to provide the MFP.

The pilot's guidance, however, lacks the specificity to ensure these statutory protections are upheld. This ambiguity could be interpreted to allow manufacturers to improperly deny 340B rebates whenever an MFP applies, even in cases where the MFP is higher than the 340B ceiling price. This lack of guardrails risks both improper denial of valid rebates and the inconsistent application of statutory protections, which would directly harm health centers and their patients. **MCR Health strongly urges OPA to revise the pilot guidance to explicitly map each allowable denial of claims to the corresponding statutory provision in the IRA**. The guidance must also define the specific calculation methodology for non-duplicated amounts and require claim-level documentation for all denials based on MFP duplication. This is essential to ensure that the pilot does not inadvertently create barriers to care by enabling manufacturers to violate federal law.

Additionally, the proposed 340B claims repository, as outlined in the CY2026 Medicare Physician Fee Schedule, would require covered entities to submit detailed, claim-level data on 340B drugs dispensed under Medicare Part D. While this is intended to help CMS exclude 340B-purchased units from inflation rebate calculations under the IRA, it would create new and ongoing reporting requirements for health centers. This will require further investments in staff administrative responsibilities, IT infrastructure, and vendor management, which will ultimately divert resources away from direct patient care.

If finalized in tandem with OPA's proposed rebate model, these changes would create an unsustainable level of strain on health centers. The rebate model would force health centers to wait extended time periods for vital 340B revenue. At the same time, the new IRA-related reporting requirements would add to an already strained administrative workload. These two sets of proposals, though seemingly separate, would compound the administrative and financial burdens on health centers, hindering their ability to provide crucial care. **To ensure a functional and compliant system, HRSA must provide a clear and comprehensive plan that addresses how its pilot program will work in harmony with the statutory requirements of the Inflation Reduction Act.**

B. BIN/PCN Data Is Not Essential for the Deduplication of 340B and MFP Discounts.

MCR Health respectfully urges OPA not to include Bank Identification Number (BIN) and Processor Control Number (PCN) as permitted data elements for the pilot's pharmacy claim

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submissions. Requiring this data would create an unnecessary administrative burden for health centers without providing any enhanced program integrity.

This request is based on the following critical points:

- **Inconsistency with CMS and Prevailing Manufacturer Requirements:** CMS has not included BIN/PCN in the required data elements for 340B deduplication of Medicare Part D inflationary penalties. In fact, a majority of manufacturers (38 of 39) with existing 340B contract pharmacy restrictions also do not require BIN/PCN. Aligning the 340B rebate pilot's data specifications with these prevailing standards will promote consistency across the industry and avoid imposing non-essential, unique reporting requirements on health centers.

- **Operational Impossibility for a Key Patient Population:** BIN/PCN are limited to retail prescription claims with insurance coverage. They are frequently unavailable for prescriptions filled for uninsured individuals who pay with cash or use a health center's sliding fee scale program. Requiring this data would effectively exclude a core portion of the patient population that health centers serve, creating an operational barrier for a model intended to be transparent and comprehensive. BIN/PCN fields are also not used for clinic-administered or physician-dispensed medications, further limiting their applicability.

- **Data Inaccuracy and Administrative Inefficiency:** Plan sponsors, not covered entities, are the reliable source for BIN/PCN data. Manufacturers receive these values directly from plan sponsors. Forcing health centers to provide this data introduces an unnecessary potential for inaccuracy and administrative inefficiency. This information is also subject to change post-adjudication, making covered entities an inherently less accurate source. Deduplication can be effectively achieved using other claim-level identifiers listed in the HRSA notice, without imposing this additional burden on covered entities.

MCR Health strongly encourages OPA to remove BIN/PCN from the allowable pharmacy claim data fields that can be requested. This approach would better align the pilot with anticipated CMS standards and prevailing manufacturer requirements, ensuring the pilot's success without creating an unneeded burden on health centers.

C. Limiting the Scope of Manufacturer Data Requests

While not explicitly defined in the pilot program, the opportunity for manufacturers to request purchasing data presents a significant and unnecessary administrative burden on health centers. The precedent has already been set, as Johnson & Johnson's proposed rebate model included a provision to request purchasing data directly from covered entities.

Johnson & Johnson proposed in their initial rebate model,[10] published August 23, 2024, that they would be requesting purchasing data from covered entities:

[10] https://beaconchannelmanagement.com/pages/resources (Johnson & Johnson Policy Documents)

*DSH Covered Entities will submit standard information about the **purchase** and dispense or administration of STELARA and XARELTO that Covered Entities collect, report, and maintain in the normal course of business."*

It is reasonable to anticipate that similar requests will be made again in future rebate models. **To avoid placing this unnecessary burden on health centers, MCR Health respectfully suggests that purchasing data be made available to manufacturers from other reliable sources.** The 340B Prime Vendor Program, Apexus, has access to the vast majority of 340B purchasing data. The remaining data would primarily result from direct purchases from the manufacturers, who would already have access to this information.

Given the major disruption the 340B rebate program is anticipated to have on health centers, a system that forces health centers to provide data that is already accurately and readily available from other sources is not only redundant but also adds additional administrative burdens on safety-net providers. It is imperative that HRSA leverage existing resources to protect the stability of the safety-net providers that the 340B program was designed to support.

D. Limit the 340B Rebate Model Pilot to Retail Pharmacy Claims Only

MCR Health strongly urges OPA to reconsider applying the pilot program to all areas of 340B. While OPA recognizes that a rebate model could fundamentally shift how the 340B Program has operated for over 30 years, its decision to apply the pilot to all outpatient settings, including physician- and clinic-administered drugs, is a significant overreach for an untested pilot program.

This broad approach is fundamentally at odds with the current statutory landscape. Until 2028, the Medicare Drug Price Negotiation Program (MDPNP) Maximum Fair Prices (MFP) only apply to the retail claim setting.[11] This means there is no risk of duplicate discounts with MFPs outside of the retail setting for at least the next two years. Extending the pilot program to non-retail claims—where no duplicate discount risk currently exists would create a major disruption to health centers and their patients for no clear benefit.

Given the major disruption the rebate model will bring and the lack of risk of 340B and MFP claim duplication outside of the retail setting until 2028, we encourage OPA to limit the pilot program to claims and purchases made in the retail space for at least the initial year. This measured approach would allow covered entities time to adapt to the new model in a single setting, while still addressing the primary driver of the pilot program: preventing duplicate discounts. This limitation is essential to prevent significant harm to health centers, which serve as the nation's safety-net providers, while HRSA evaluates this untested model.

E. Preserving Flexibility in a New Rebate Model: Unit or Package-level Rebates

Historically, the 340B Program has been intentionally flexible to accommodate the significant variance in covered entity types and organizational structures. **With manufacturers now able to**

[11] https://www.hrsa.gov/opa/340b-model-pilot-program

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define rebate models within the 340B Rebate Model Pilot Program, we anticipate that covered entities will lose much of this flexibility, including the ability to choose the purchasing model that best fits their needs. This shift represents a significant departure from the program's history and poses a threat to the health centers' ability to participate successfully.

In preparing these comments, we considered the benefits and drawbacks of unit- and package-level rebate models and concluded that there is no "one-size-fits-all" solution. Each approach introduces its own set of administrative and financial challenges for health centers.

- **Unit-Level Accumulation and Rebating:** This approach has the benefit of mirroring the vetted process used by state Medicaid agencies, which could allow for more timely payments and prevent delays in receiving a rebate when a full package size is not met. However, it introduces significant challenges for the more than 90% of health center-owned pharmacies that operate with physical inventories. In this scenario, expired or wasted inventory that is not tied to a patient's dispensation would result in a lost rebate, increasing costs for health centers. It is unclear if a process similar to the JW (Waste) billing modifiers used in Medicare Part B would be allowed under this pilot to mitigate this financial risk.

- **Package-Level Accumulation and Rebating:** This model would be beneficial if it tied rebates to purchases rather than individual patient dispensations, which aligns more closely with physical inventory models. However, we anticipate challenges if dispensation data does not match purchasing data, as has been experienced with 340B ESP and current contract pharmacy restrictions. This could lead to manufacturer platform algorithms rejecting valid claims, particularly for slow-moving medications, which are a common part of normal pharmacy operations. It also risks significant delays in payment as health centers wait for a full package size to be dispensed, or worse, not being paid at all if the package size is not met within a manufacturer-defined timeframe. As some have noted, under this model, health centers could be waiting 10 years to receive a rebate.

Ultimately, MCR Health cannot recommend one scenario over the other, as both present significant financial and operational burdens. **We, therefore, request that OPA consider the need for flexibility in the application of these rebate models. Any approved model must include safeguards to minimize waste and the financial impact on health centers**. We specifically request that OPA be cautious in approving models with limited timeframes for entities to accumulate toward a full package size, as this will result in additional costs to health centers through lost rebate opportunities.

IV. MCR Health Strongly Urges HRSA to Create More Safeguards for Covered Entities and Their Patients

MCR Health has serious concerns that the proposed pilot program lacks adequate enforcement mechanisms to hold drug manufacturers accountable. Health centers and their patients cannot afford to operate on an "honor system" when patient access to affordable medications has been significantly curtailed through ongoing contract pharmacy restrictions. The recent D.C. District

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Court ruling reinforces that HRSA has the statutory authority to "superintend" and "control" the 340B Program, and that a formal dispute resolution process is a key part of that authority.

The proposed pilot program, in its current form, presents several key deficiencies regarding enforcement and accountability:

- **Lack of Explicit Enforcement and Penalties:** The guidance provides no explicit progressive enforcement or penalties for manufacturers if they fail to provide a rebate within the 10-day timeframe. The 340B statute, however, explicitly provides for sanctions for noncompliance, including liability for underpayment of drugs. Without clear consequences, this pilot risks becoming a mechanism for manufacturers to unilaterally withhold discounts and engage in "unbridled self-enforcement."

- **Insufficient Communication and Dispute Resolution:** The pilot lacks an official and effective communication channel for covered entities. The 340B statute and historical guidance require a formal dispute resolution process, with HRSA playing a central, decision-making role. Relying on a simple email inbox is a direct contradiction of this established "unitary administrative and enforcement scheme."

- **Unreasonable Compliance Timeline:** Providing health centers with only 60 days to comply with a manufacturer's rebate model pilot plan creates an extreme administrative burden and operational challenges. A core principle of the 340B program is that any anti-fraud efforts must "minimize the administrative and financial burdens" on covered entities. This short timeline is destined to create a variety of challenges that will directly impact patients' access to affordable medications.

To address these critical issues, MCR Health recommends that OPA establish a **stakeholder advisory panel** to ensure that the feedback and concerns of covered entities are formally and consistently addressed. This panel should include pharmacists with the necessary subject matter expertise to understand the complexities of pharmacy software, billing, and data components. The 340B statute explicitly provides for sanctions for noncompliance, including liability for underpayment of drugs. It also outlines a formal dispute resolution process with HRSA to handle grievances. **MCR Health is concerned that the pilot program fails to provide such protections, leaving health centers without recourse if rebates are improperly denied or delayed.** Without clear protections, the pilot program risks becoming a mechanism that benefits manufacturers at the expense of the safety-net providers it was created to support.

V. Conclusion

MCR Health strongly urges HRSA to exempt Community Health Centers from the 340B Rebate Model Pilot Program. This pilot, as currently proposed, represents a fundamental departure from the original intent of the 340B program—to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. The retrospective rebate model would impose immense administrative, financial, and operational burdens on health centers, hindering their ability to provide essential services to the 34 million Americans who rely on them.

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As we have detailed, this model would create significant cash flow challenges, forcing health centers to make difficult decisions about staffing, services, and the range of drugs they can afford to stock. It also creates a new barrier for patients, especially uninsured patients, who depend on the up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law.

Given the existing, robust compliance and oversight framework already in place for health centers, we believe this pilot would cause disproportionate harm to the very providers the program was designed to support. Instead of enhancing program integrity, the pilot's lack of clear enforcement, conflicting statutory requirements, and burdensome data demands will only create an untenable system that puts patient access at risk. **We urge HRSA to reconsider its approach and ensure that the future of 340B protects, rather than harms, the most vulnerable patients**.

MCR Health appreciates the opportunity to respond to this 340B rebate model pilot program and looks forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact Randy Heiser, VP Pharmacy rheiser@mcr.health.

Sincerely,

Randy Heiser

Vice President, Pharmacy

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. ROBERT F. KENNEDY, JR. SECRETARY of the U.S. Department of Health and Human Services, *et al.*, Defendants.	No. 2:25-cv-600-JAW

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION[1]

[1] Counsel for Defendants conferred with counsel for Plaintiffs, and the parties have agreed to litigate the Motion for a Temporary Restraining Order, *see* Doc. No. 3, as a Preliminary Injunction Motion on the schedule the Court has entered, *see* Doc. Nos. 31, 32.

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INTRODUCTION

Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires pharmaceutical manufacturers participating in Medicare Part B and Medicaid to sell drugs at reduced prices to certain healthcare providers known as "covered entities." The statute provides that "the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary [of Health and Human Services (HHS)]) to the manufacturer for covered outpatient drugs" may not exceed a ceiling price set by a statutory formula. *See* 42 U.S.C. § 256b(a)(1). Manufacturers sign a pharmaceutical pricing agreement with the Secretary of HHS signifying their intent to participate in the 340B Program and memorializing their obligation to offer covered entities drugs for purchase at or below the ceiling price.

Until now, with the exception of State AIDS Drug Assistance Programs, participating manufacturers have provided upfront discounts—meaning that covered entities would purchase drugs from manufacturers at the ceiling price. But recent inquiries from stakeholders, and developments in the statutory and regulatory landscape, have prompted the agency to consider whether a rebate model might offer advantages. Under a rebate model, covered entities would purchase drugs at their retail price, or wholesale acquisition cost, and then submit a rebate claim to the manufacturer for the difference between that price and the 340B ceiling price.

The statute plainly gives the agency the authority to choose between rebates or discounts. *See* 42 U.S.C. § 256b(a)(1) (stating that "the amount required to be paid (taking into account any rebate or discount, *as provided by the Secretary*") may not exceed the ceiling price (emphasis added)). But recognizing that the 340B Program has operated via upfront discounts for a long time, and wanting to learn more about the advantages and disadvantages of a rebate model, HHS decided to test the rebate model on a small scale. It established a 340B Rebate Model Pilot Program to test the model on ten specific drugs. It then solicited comments from stakeholders along with applications from manufacturers of those ten drugs seeking to participate in the program. After reviewing the comments and applications, the agency approved eight manufacturers to begin selling the chosen drugs to

covered entities under a rebate model as of January 1, and one manufacturer to do the same as of April 1. The agency's actions here amount to a reasonable way to test an action that is plainly authorized by statute.

Yet Plaintiffs—covered entities and associations representing them—seek emergency relief from this Court to thwart the implementation of the Pilot Program, alleging that the program is substantively unreasonable in violation of the Administrative Procedure Act (APA). But under the APA, Plaintiffs must challenge discrete, final agency action, not broad, ongoing programs or policies. *See Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 882 (1990). At most, Plaintiffs may seek to challenge the agency's approval of the nine manufacturers' applications to offer 340B prices for select drugs through a rebate mechanism. But the 340B statute gives the agency discretion to choose between rebates or discounts, and it provides no standards for a court to judge the exercise of that discretion. So the decisions to approve those manufacturers' applications is "committed to agency discretion by law" and is therefore unreviewable. 5 U.S.C. § 701(a)(2).

Even if the approvals were subject to review under the APA, they can only be set aside if they were "arbitrary" or "capricious." *Id.* § 706(2)(A). But these decisions were neither—the agency considered all important aspects of the problem, took into account any reliance interests and costs of covered entities, weighed possible alternatives, and factored in perspectives of other stakeholders before deciding to approve the manufacturers' applications.

Finally, Plaintiffs have failed to show irreparable harm, and the balance of equities and public interest weigh in the Government's favor. Therefore, Plaintiffs' motion for a preliminary injunction should be denied.

BACKGROUND

I. Statutory and Regulatory Background

Medicare is a federal medical insurance program for people ages sixty-five and older and for younger people with certain disabilities. *See* 42 U.S.C. §§ 1395 *et seq*. Medicaid is a joint federal and state program that provides medical coverage for people with limited resources or certain disabilities. *See id.* §§ 1396 *et seq*.

A. The Section 340B Program

Since 1990, pursuant to the Medicaid Drug Rebate Program, pharmaceutical manufacturers that participate in Medicaid have been required to "provide rebates to States on their Medicaid drug purchases." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 114 (2011); *see* 42 U.S.C. § 1396r-8. These rebates provide States with a discount, which for most "brand-name drugs" is equivalent to the difference between the average wholesale price and the lowest price at which the manufacturer sells the drug, known as the "best price." *See id.* § 1396r-8(c); 42 C.F.R. pt. 447.

The creation of the Medicaid Drug Rebate Program gave rise to a concern that manufacturers had reduced the discounts they were giving to safety-net providers in order to raise the "best price" figures for their drugs under Medicaid and lower their rebate payments to States. *See* H.R. Rep. No. 102-384(II), at 10-12 (1992). Congress responded by creating the 340B Program to govern the prices that drug manufacturers may charge providers that offer health care to underserved individuals, *see* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967 (codified at 42 U.S.C. § 256b), and it later expanded the scope of that program, *see* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, tit. VII, subtitle B, § 7101, 124 Stat. 119, 821 (2010). Within the Department of HHS, the Health Resources and Services Administration (HRSA) administers the 340B Program on behalf of the Secretary.

Under Section 340B, pharmaceutical manufacturers participating in Medicaid and in Medicare Part B (which covers certain outpatient drugs) "must offer discounted drugs to covered entities,

dominantly, local facilities that provide medical care for the poor." *Astra USA,* 563 U.S. at 115; *see* 42 U.S.C. § 256b(a)(1), (3), (4). Covered entities include, for example, federally qualified health centers, certain children's hospitals and free-standing cancer hospitals, critical access hospitals, rural referral centers, black lung clinics, and other federally funded health care entities. 42 U.S.C. § 256b(a)(4). The discounts provided through the 340B Program help covered entities "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12. In particular, it gives them extra revenue from serving insured patients because covered entities "turn a profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount." *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 699 (3d Cir. 2023), *entering judgment*, 2023 WL 1325507 (3d Cir. Jan. 30, 2023). And it allows them "to give uninsured patients drugs at little or no cost." *Id.*

Section 340B implements these discounted-pricing requirements through "uniform agreements that recite the responsibilities [Section] 340B imposes, respectively, on drug manufacturers and the Secretary of HHS." *Astra USA*, 563 U.S. at 113. These "are not transactional, bargained-for contracts" but rather "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them." *Id.* at 113, 118. As relevant here, Section 340B directs the Secretary to enter into agreements providing that "the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs . . . purchased by a covered entity" may not exceed a specified ceiling price. 42 U.S.C. § 256b(a)(1). For covered outpatient drugs, the ceiling price is equivalent to the average manufacturer price less the rebate the manufacturer provides to States. *Id.* § 256b(a)(1)–(2); 42 C.F.R. § 10.10.

Section 340B also imposes substantive requirements on covered entities that choose to participate in the program, prohibiting (1) duplicate discounts and (2) the diversion of drugs purchased under the 340B Program. 42 U.S.C. § 256b(a)(5). To prevent duplicate discounts, the statute specifies that a covered entity shall not request a discount for a drug that is already subject to a separate

Medicaid rebate requirement. *Id.* § 256b(a)(5)(A). And to prevent diversion, the statute specifies that "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). Disputes between manufacturers and covered entities may be resolved through an administrative process. *See id.* § 256b(d)(3); 42 C.F.R. §§ 10.20-10.24.

To ensure compliance, Section 340B requires a covered entity to permit both the Secretary and the manufacturer to audit the entity's records. *Id.* § 256b(a)(5)(C). Congress authorized the Secretary to impose sanctions against covered entities—including civil monetary penalties, removal from the 340B Program, and referral to other federal agencies for appropriate action—for diversion, duplicate discounts, or other violations of Program requirements. *Id.* § 256b(d)(2)(B)(v).

If a manufacturer fails to comply with its 340B requirements, the Secretary of HHS may terminate the manufacturer's pharmaceutical pricing agreement, "which terminates as well the manufacturer's eligibility for Medicaid coverage of its drugs," and may impose civil penalties. *Astra USA*, 563 U.S. at 115–16; *see* 42 U.S.C. §§ 256b(d)(1)(B)(vi), 1396r-8(b)(4)(B)(i), (v).

B. The Medicare Drug Price Negotiation Program

In the Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818, Congress gave the Secretary authority to negotiate the prices that Medicare pays for pharmaceutical products that lack generic competition and that account for a disproportionate share of Medicare's expenses. 42 U.S.C. §§ 1320f(a), 1320f-1(b), (d), (e). The Medicare Drug Price Negotiation Program applies only to manufacturers that choose to participate in Medicare and Medicaid and governs only the prices that Medicare pays for certain drugs. *See id.* § 1320f-1(b), (d). If negotiations for a selected drug are successful, the manufacturer memorializes its agreement to make the drug available to Medicare beneficiaries at the negotiated price, called the "Maximum Fair Price." *Id.* § 1320f-2(a). In the first negotiation cycle, the Secretary reached agreements for negotiated prices with participating drug companies for ten selected drugs, and those prices take effect January 1, 2026.

Under the Inflation Reduction Act's "nonduplication" provision, manufacturers must provide access to the lower of the Maximum Fair Price or the 340B ceiling price to covered entities—but not both. *Id.* § 1320f-2(d). Deduplication refers to the process of preventing such duplicate discounts.

II. Factual Background

On July 31, 2025, HRSA issued a press release announcing the availability of a 340B Rebate Model Pilot Program for the ten drugs on the Centers for Medicare & Medicaid Services (CMS) Medicare Drug Price Negotiation Selected Drug List for year 2026.[2] In the press release, HRSA explained that it was seeking to test the rebate model "in a methodical and thoughtful" way "to ensure a fair and transparent 340B rebate model process." *See* HRSA Press Release.

The next day, HRSA published a notice in the Federal Register announcing the application process for the Pilot Program. *See* 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program, 90 Fed. Reg. 36,163 (Aug. 1, 2025). The notice explained that the agency had received inquiries from manufacturers related to different proposed rebate models for the 340B Program, primarily to address 340B and Maximum Fair Price deduplication, but also to facilitate other aims including preventing diversion.

Indeed, manufacturers previously tried to implement rebate models unilaterally, *see, e.g.*, *Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630 (D.D.C. May 15, 2025), *appeal filed sub nom. Novartis Pharms. Corp. v. Kennedy*, No. 25-5117 (D.C. Cir. May 21, 2025); *consolidated with Johnson & Johnson Health Care Sys. Inc. v. Kennedy*, 2025 WL 1783901 (D.D.C. June 27, 2025), *appeal filed*, No. 25-5236 (D.C. Cir. June 30, 2025). In that litigation, as here, the Government's position is that implementing a rebate model requires agency approval. *See* 42 U.S.C. § 256b(a)(1).

In the notice, HRSA explained that the point of the Pilot is to test the rebate model in a thoughtful manner and help the agency better understand the merits and shortcomings of the rebate

[2] *See* Press Release, HRSA, HRSA Announces Application Process for the 340B Rebate Model Pilot Program and Request for Public Comment (July 31, 2025), https://www.hrsa.gov/about/news/press-releases/rebate-model-pilot-program ("HRSA Press Release").

model, as well as inform considerations for any future rebate models. 90 Fed. Reg. at 36,163–64. The potential scope of the program would be limited to the ten drugs included on the Medicare Drug Price Negotiation Selected Drug List for year 2026. Those drugs represent only 2% of 340B sales. *See* Decl. of Chantelle Britton ¶ 22 ("Britton Decl."). The notice solicited comments from stakeholders and applications from manufacturers of the selected drugs. It also set forth requirements for manufacturers' plans for participation. Comments were due September 8, 2025, *see* 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program; Correction, 90 Fed. Reg. 38,165 (Aug. 7, 2025), and applications were due the following week, on September 15, 2025. Manufacturers whose plans were approved would have to give covered entities at least 60 calendar days' notice before implementation of an approved rebate model. HRSA also addressed questions about the Pilot Program on its website.[3]

In response to the notice, HRSA received more than 1,100 comments and nine applications from manufacturers. On October 30, 2025, HRSA announced eight manufacturers that were approved to participate in the Pilot Program with a January 1, 2026 effective date. A ninth manufacturer was later approved to participate in the Program beginning on April 1, 2026. The January 1, 2026, effective date applicable to the majority of participants was chosen to align with the date that negotiated prices for those same drugs would take effect under the Medicare Drug Price Negotiation Program.

III. This Litigation

On December 1, 2025—approximately four months after HRSA first announced the 340B Rebate Model Pilot Program and one month after the agency announced the approval of certain manufacturers' applications—Plaintiffs filed this lawsuit to challenge the 340B Rebate Model Pilot Program under the APA. *See* Compl., Doc. No. 1. That same day, Plaintiffs moved for a temporary restraining order, arguing that the Pilot Program violates the APA because it is arbitrary and capricious

[3] HRSA, 340B Drug Pricing Program, FAQs, https://www.hrsa.gov/opa/faqs?categories=All&keywords= (last visited Dec. 15, 2025).

and substantively unreasonable. *See* Mot. for a TRO with Incorporated Mem. of Law, Doc. No. 3 ("Pls.' Br."). Plaintiffs seek an order prohibiting the Pilot Program from going into effect pending a final ruling on the merits of this case.

STANDARD OF REVIEW

A preliminary injunction is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). A "plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Id.* at 20. The third and fourth factors "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). The plaintiff bears the burden of demonstrating those requirements. *Nieves-Marquez v. Puerto Rico*, 353 F.3d 108, 120 (1st Cir. 2003).

To "demonstrate likelihood of success on the merits, plaintiffs must show 'more than mere possibility' of success—rather, they must establish a 'strong likelihood' that they will ultimately prevail." *Sindicato Puertorriqueño de Trabajadores v. Fortuño*, 699 F.3d 1, 10 (1st Cir. 2012) (per curiam) (citation omitted). And a preliminary injunction cannot issue on the basis of speculative or possible harm. Rather, the moving party must establish that irreparable harm is "*likely* in the absence of an injunction." *Winter*, 555 U.S. at 22.

ARGUMENT

Plaintiffs challenge the establishment and implementation of the 340B Rebate Model Pilot Program, but that is an impermissible programmatic challenge under *Lujan*, 497 U.S. at 882 (holding that a program is not an "agency action" within the meaning of 5 U.S.C. § 702, much less a "final agency action" within the meaning of 5 U.S.C. § 704). In the same vein, the notice announcing the Pilot Program and soliciting comments and applications is not itself final agency action: if no manufacturers had applied (or no applications had been approved), the Pilot Program would have no

effect on anyone. At most, Plaintiffs may seek to challenge the agency's approval of the nine manufacturers' applications to offer 340B prices for select drugs through a rebate mechanism. Because the 340B statute gives the Secretary of HHS discretion to choose between rebates or discounts, and provides no standard by which to judge the exercise of that discretion, the decision to approve those applications is committed to agency discretion by law and thus unreviewable. Even if the approvals were subject to review under the APA, they can only be set aside if they were "arbitrary" or "capricious." 5 U.S.C. § 706(a)(2)(A). But these decisions were neither: the agency made a reasonable decision "to test the rebate model," which many stakeholders had been requesting, "on a select group of drugs . . . in a methodical and thoughtful" way to ensure fairness for all stakeholders. 90 Fed. Reg. at 38,165. And it did so after considering important aspects of the problem, including any reliance interests, costs, and alternatives raised in the comments. Finally, Plaintiffs have failed to show irreparable harm, and the balance of the equities and public interest weigh in the Government's favor.

I. The Government is Likely to Succeed on the Merits

A. The Pilot Program is Not Discrete, Final Agency Action Subject to Review Under the APA

At the outset, Plaintiffs broadly seek to challenge HRSA's establishment and implementation of the 340B Rebate Model Pilot Program. *See generally* Compl., Prayer for Relief (seeking to "set aside" the Pilot Program); Pls.' Br. at 20 (asking this Court to prohibit the Pilot Program from going into effect).

The APA requires Plaintiffs to challenge discrete and final agency action, not seek "*wholesale* improvement of [a] program by court decree." *Lujan*, 497 U.S. at 891; *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (explaining that final agency action marks the completion of the agency's decision-making process and the decision is one that determines rights or obligations, or from which legal consequences will flow). In *Lujan*, the plaintiffs challenged a series of land-use decisions, which they referred to as the "land withdrawal review program." 497 U.S. at 890. The Supreme Court rejected the challenge, holding that the plaintiffs must "direct [their] attack against some particular 'agency

action' that causes [them] harm." *Id.* at 891. The Court explained that the so-called "program" was not an identifiable final agency action but shorthand for the agency's ongoing "operations . . . in reviewing withdrawal revocation applications and the classifications of public lands and developing land use plans as required by [statute]." *Id.* at 890. The Court stressed that any "flaws in the entire 'program'—consisting principally of the many individual actions referenced in the complaint, and presumably action yet to be taken as well—cannot be laid before the courts for wholesale correction under the APA." *Id.* at 893.

Other courts have applied these principles to conclude that, because "'an on-going program or policy is not, in itself, a final agency action under the APA,' [a court's] jurisdiction does not extend to reviewing generalized complaints about agency behavior." *Cobell v. Kempthorne*, 455 F.3d 301, 307 (D.C. Cir. 2006) (citation omitted). Similarly, "implementation" of such a program or policy "is neither agency action nor final agency action subject to judicial review under the APA." *Vill. of Bald Head Island v. U.S. Army Corps of Eng'rs*, 714 F.3d 186, 195 (4th Cir. 2013). These APA limitations serve to "protect agencies from undue judicial interference with their lawful discretion, and to avoid judicial entanglement in abstract policy disagreements which courts lack both expertise and information to resolve." *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 66 (2004) ("*SUWA*").

Under these principles, Plaintiffs' challenge as they frame it cannot proceed. The Pilot Program itself is not a circumscribed, discrete agency action subject to review under the APA. As in *Lujan*, the program does not refer to a particular agency order or regulation. Rather, it is shorthand for the agency's continuing operations in administering the 340B Program—principally through agreements with individual manufacturers to effectuate 340B prices, which Congress specified may be achieved through rebates or discounts "as provided by the Secretary." 42 U.S.C. § 256b(a)(1).

Moreover, "implementation" of the Pilot Program is neither agency action nor final agency action. *See Vill. of Bald Head Island*, 714 F.3d at 195. No rights or obligations are determined by the existence of the program itself. *See Bennett*, 520 U.S. at 177–78. Similarly, the notice announcing the

Pilot Program and soliciting comments and applications is not final agency action either: if no manufacturers had applied or been approved, the Pilot Program would have no effect. Yet the key question Plaintiffs invite the Court to answer is "why it is necessary to implement the program this way," Pls.' Br. at 10; *see also id.* at 20 (requesting that the Court prohibit Defendants from implementing the program). That is precisely the kind of question that federal courts are not suited to answer. *See SUWA*, 542 U.S. at 66.

What Plaintiffs really take issue with is the agency's decisions to allow nine drug manufacturers to offer 340B pricing for ten selected drugs via rebates. Those approvals constitute informal agency actions—specifically, informal agency adjudications. *See, e.g.*, *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971) (decision of the Secretary of Transportation to approve the routing of an interstate highway through Overton Park was informal agency action); *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (decision concerning applications for new banking authorities was informal agency action); *see also Izaak Walton League of Am. v. Marsh*, 655 F.2d 346, 361 n.37 (D.C. Cir. 1981) ("Informal adjudication is a residual category including all agency actions that are not rulemaking and that need not be conducted through 'on the record' hearings."). Because those approvals are final agency actions, *see Bennett*, 520 U.S. at 177–78, Plaintiffs may seek to challenge those decisions. *See* Compl. ¶ 29 (challenging HRSA's establishment and implementation of the Pilot Program, as well as its approval of drug company applications). But Plaintiffs cannot "seek *wholesale* improvement of this program by court decree," *Lujan*, 497 U.S. at 891.

B. The Decisions to Approve the Applications to Participate in the Pilot Program are Committed to Agency Discretion by Law

The decision to effectuate 340B prices via rebates is committed to agency discretion by law. Agency action "committed to agency discretion by law" is exempt from APA review. *See* 5 U.S.C. § 701(a)(2); *Heckler v. Chaney*, 470 U.S. 821, 830–31 (1985). A statute need not expressly preclude review for the agency's action to be committed to agency discretion. Rather, "[a] statute [may be] drawn so that a court would have no meaningful standard against which to judge the agency's exercise

of discretion." *Heckler*, 470 U.S. at 830. In that case, the statute leaves nothing for the courts to review. The Supreme Court applied these principles in *Webster v. Doe* to a statute allowing the director of the CIA to terminate an employee whenever he "shall *deem* such termination necessary or advisable in the interests of the United States." 486 U.S. 592, 600 (1988). Because that assessment was "the Director's alone" to make, the statute "foreclose[d] the application of any meaningful judicial standard of review." 486 U.S. 592, 600, 603 (1988); *see also Lincoln v. Vigil*, 508 U.S. 182, 192 (1993) (allocation of funds from a lump-sum appropriation was committed to agency discretion because of the absence of instructions regarding how to spend it); *CC Distribs., Inc. v. United States*, 883 F.2d 146, 153 (D.C. Cir. 1989) (statute directing the Secretary of Defense to procure services from the private sector if less expensive—except for services the Secretary "determines must be performed by military or governmental personnel"—left the decision of which services must be performed by government employees to the Secretary's determination).

The 340B statute directs the Secretary of HHS to enter into agreements with drug manufacturers to effectuate the 340B ceiling price, "taking into account any rebate or discount, *as provided by the Secretary*." 42 U.S.C. § 256b (emphasis added). The relevant definition for the term "provide" is "to have as a condition" or to "stipulate." *Provide*, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/provide. The statute therefore contemplates that the Secretary will set "as a condition" or "stipulate" whether the 340B price will be achieved through rebates or discounts. *See also Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630, at *9 (D.D.C. May 15, 2025) (adopting this construction of the statute). Moreover, the statute provides no guidelines by which to judge the Secretary's choice. And the legislative history confirms this understanding of the text: the House Committee on Energy and Commerce report accompanying the 1992 legislation noted that 340B price reductions "would be implemented, *at the discretion of the Secretary*, either by a point-of-purchase discount, a rebate, or other mechanism." H.R. Rep. No. 102-384(II), at 8, 12, 16 (emphasis added). As in *Webster*, the decision at issue is the Secretary's alone to make. *See Webster*, 486 U.S. at

603. And because the statute does not provide a benchmark against which to measure the agency's exercise of discretion in making that decision, arbitrary and capricious review does not apply.

C. Even if the Decisions to Approve the Applications Were Reviewable, They Do Not Violate the APA

Even if review were not precluded here, the agency's decisions can be overturned only if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Review under the "arbitrary and capricious" standard is "narrow," and the ultimate question is whether the agency's action was reasonable. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009). Review should be particularly circumscribed here because the statute "exudes deference" to the Secretary's determination as to whether to effectuate 340B prices via rebates or discounts, *see Webster*, 486 U.S. at 600, and the approvals are designed to test the rebate model on a small scale to minimize the costs and risks of such information gathering.

To comply with the arbitrary and capricious standard, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a "rational connection between the facts found and the choice made." *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962). Moreover, an agency is free to change its position so long as it displays awareness that it is doing so, shows that there are good reasons for the new policy, and takes any serious reliance interests into account. *See Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221–22 (2016). In conducting its review, the Court should consider "whether there has been a clear error of judgment," *Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc.*, 419 U.S. 281, 285 (1974) (quoting *Volpe*, 401 U.S. at 416). But "a court is not to substitute its judgment for that of the agency." *Fox Television Stations, Inc.*, 556 U.S. at 513–14 (citation omitted).

Here, the agency's decisions to approve the manufacturers' applications readily satisfy how courts apply the arbitrary and capricious standard in the context of informal agency adjudications.[4]

[4] *See, e.g.*, *Royal Siam Corp. v. Chertoff*, 484 F.3d 139, 148 (1st Cir. 2007) ("In the absence of an error of law—and we see none here—this case comes down to straight abuse-of-discretion review. Under that standard, the outcome is foreordained."); *Neustar, Inc. v. FCC*, 857 F.3d 886, 900 (D.C. Cir. 2017)

First, as explained in the agency's notice, the agency previously received a significant amount of feedback from both manufacturers and covered entities regarding rebate models, and recognized that a rebate model "could fundamentally shift how the 340B Program has operated for over 30 years." 90 Fed. Reg. at 36,164. Still, the agency wanted to better understand the merits and shortcomings of a rebate model from stakeholders' perspectives, and to inform consideration of any future 340B rebate models consistent with the 340B statute and the Administration's goals. *Id.* So it designed a thoughtful pilot program that was limited in scope to only ten drugs that account for only 2% of 340B sales, *see* Britton Decl. ¶ 22,[5] to test "a fair and transparent 340B rebate model process for all stakeholders involved." 90 Fed. Reg. at 36,164. Further, because one of the goals of the Pilot Program is to address 340B and Maximum Fair Price deduplication, the agency chose to limit the scope of the Pilot to the ten drugs with negotiated Maximum Fair Prices set to take effect on January 1, 2026, due to their inclusion in the Medicare Drug Price Negotiation Program. After reviewing applications to participate in the Pilot Program from manufacturers of those drugs, as well as comments received from stakeholders including covered entities, the agency carefully balanced the equities and then decided which specific aspects of each application to approve. *See* Britton Decl. ¶ 12–14. Those decisions were reasonable.

1. In opposition, Plaintiffs first argue that the agency's actions were arbitrary and capricious because Defendants offered no reasonable explanation for instituting the Pilot Program and ignored reliance interests by healthcare providers. Pls.' Br. at 9–11. But as explained above, the agency did offer a reasonable explanation: "[d]ue to the significant amount of feedback received from (or on behalf of) manufacturers and covered entities regarding implementation of rebate models," the agency

(although Petitioner raised legitimate concerns that might have justified a different decision by the agency, the Court was "not to substitute [its] judgment for that of the [agency] . . . . Rather, the question [of whether the agency acted arbitrarily and capriciously] is more narrow").

[5] *Compare Clifford v. Pena*, 77 F.3d 1414, 1418 (D.C. Cir. 1996) ("[T]here is nothing improper in receiving declarations that merely illuminate reasons obscured but implicit in the administrative record[.]" (citation modified)) *with Overton Park, Inc*, 401 U.S. at 419 (discouraging reliance on "mere[] 'post hoc' rationalizations" (citation omitted)).

wanted to test the merits and shortcomings of a rebate model, including whether it was beneficial in addressing "340B and Maximum Fair Price (MFP) deduplication" and "the prevention of 340B Medicaid duplicate discounts and diversion." 90 Fed. Reg. at 38,165. That course of action is consistent with the agency's long-held positions that it must make provision for the method of obtaining the 340B statutory ceiling price, and that rebate models require more study. Consistent with those positions, the agency has not previously rejected rebate models, and has not now made a final decision about the efficacy or desirability of such models but simply announced an effort to obtain real-world data.

Still, the agency did consider the reliance interests of covered entities. It recognized that "rebate models could fundamentally shift how the 340B Program has operated for over 30 years." *Id.* So it limited the scope of the Pilot Program to a small set of manufacturers and a limited number of drugs in order to minimize the impact on covered entities. *See* Britton Decl. ¶ 5. Collectively, the ten drugs chosen for the Pilot represent only 2% of total sales in the 340B program; 340B pricing on all other drugs (representing 98% of total 340B sales) will continue to be offered through upfront discounts. And only one of the drugs selected for the Pilot Program was in the top 20 of 340B drug products purchased by covered entities in 2024. *See* Britton Decl. ¶ 22. The agency determined that further limiting the Pilot Program, either by reducing the number of drugs or covered entities in it, would interfere with the agency's ability to collect sufficient information on which to evaluate the merits and shortcomings of a rebate model. *See* Britton Decl. ¶ 22–25.

2. Plaintiffs next attack the agency's failure to respond to the comments received on the notice. Pls.' Br. at 11. Although they (correctly) do not argue that the agency was required to undertake notice and comment as a procedural matter, they assert that the agency's failure to respond to the comments is a substantive violation of the APA. Not so. As the Supreme Court held in *Perez v. Mortgage Bankers Association*, an agency's obligation to "consider and respond to significant comments received during the period for public comment" is part of the three-step procedure for notice-and-comment

rulemaking pursuant to Section 553 of the APA. 575 U.S. 92, 96 (2015). But the agency was not engaging in rulemaking here. *See supra* Argument Section I.A.[6] And even if it were, without a procedural requirement to solicit comments in the first place, the agency incurs no obligation to respond to comments, even "significant" ones. *Perez*, 575 U.S. at 96 (distinguishing between rules subject to notice-and-comment, which require that the agency respond to significant comments, and those that do not).

To be sure, if an agency chooses to solicit comments, those comments could highlight an important aspect of the problem. And an agency's failure to consider an important aspect of the problem could show that its decision was arbitrary and capricious as a substantive matter. *See Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). But the agency did not exhibit any such failure here. Contrary to Plaintiffs' contention, the agency did in fact consider the comments it received on the notice. *See, e.g.*, Britton Decl. ¶ 12. Comments submitted by different stakeholders with diverse viewpoints advocated for different changes to the program. With those diverging views in mind, the agency made reasonable judgment calls in approving applications for the Pilot Program. For example, covered entities decried having to "float" billions of dollars to drug companies during the ten-day period while awaiting their rebates, while drug manufacturers requested a longer timeframe for processing claims. *See* Britton Decl. ¶ 26. Ultimately, the agency retained the ten-day timeframe to minimize the financial impact on covered entities, reasoning that those entities would likely receive rebate payments before their invoices from wholesalers came due. *See* Britton Decl. ¶ 27–30.

As another example, in response to concerns about the denial of claims and disputed claims, the agency is planning to create a mechanism for covered entities to report to HRSA when the covered entity is unable to secure a rebate, and covered entities will be able to raise these types of issues through

[6] For that reason, Plaintiffs' reliance on *W. Coal Traffic League v. Surface Transp. Bd.*, 998 F.3d 945 (D.C. Cir. 2021) and *Marasco & Nesselbush, LLP v. Collins*, 6 F.4th 150 (1st Cir. 2021) is misplaced. *See* Pls.' Br. at 12.

the 340B Administrative Dispute Resolution process. *See* Britton Decl. ¶ 31–32. HRSA also provided a number of guardrails to mitigate these concerns, including severely limiting the bases for the denial of claims and requiring manufacturers to provide a rationale and specific documentation for any claim denials. *Id.* And Manufacturers are required to provide a customer service component and a point of contact to engage with covered entities in good faith regarding questions or concerns. *See* Britton Decl. ¶ 43.

In addition, the agency sought to balance the interests of covered entities and manufacturers by imposing several requirements on manufacturers regarding the IT platform used to collect and store rebate claims data. *See* Britton Decl. ¶ 42–43. For instance, manufacturers were required to provide covered entities at least 60 days' notice before implementing the rebate model with instructions for registering with any IT platform. *See id.* They also had to provide a technical assistance component and ensure that the data is secure, protected, and limited to the elements identified by HRSA as necessary for providing 340B rebates. *See id.*

The agency remains committed to evaluating "data and reports received from the participating manufacturers" and "covered entity and other stakeholder feedback" in order to assess the effectiveness of the Pilot in light of the issues raised by commenters. *See* 90 Fed. Reg. at 38,166.

3. Third, Plaintiffs claim that the agency ignored the scale of the Pilot Program's costs, including as compared to its benefits. *See* 90 Fed. Reg. at 38,165–66. But the agency did consider costs to covered entities, including upfront costs, administrative costs, and non-monetary costs. *See* Britton Decl. ¶ 34–41; *see also* Req. for Emergency Approval – Assessment of Administrative Burden 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, & Supporting Statement, Doc. Nos. 10-29, 10-30.[7] The agency tried to minimize those costs as much as possible by, among other things,

[7] The agency is currently examining the comments alleging an under-estimation of administrative costs in response to its Paperwork Reduction Act Notice. *See* Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-0111-Extension, 90 Fed. Reg. 44,197 (Sep. 12, 2025). The agency will address those concerns in the context of finalizing that notice. *See* Britton Decl. ¶ 35.

limiting the scope of the Pilot to ten drugs, requiring manufacturers to pay rebates within ten calendar days of submission, approving unit-level rebates, limiting the allowable data fields covered entities would need to submit to request a rebate, and imposing the costs of running the IT platform on manufacturers. *See* Britton Decl. ¶¶ 5, 27–30, 38, 43. Ultimately, the agency predicted that the Pilot Program would not have a significantly negative impact on patient care and determined that the potential significant benefits of the Pilot Program, not least of which is to test a rebate model that the Secretary is authorized by statute to adopt, outweighed the costs associated with it. *See* Britton Decl. ¶¶ 34, 41. That was a reasonable determination. The agency relied on its expertise to make a predictive judgment about costs and then made a policy decision about whether those costs were worth bearing. Such judgments are afforded substantial deference. *See FCC. v. Fox Television Stations, Inc.*, 556 U.S. 502, 521 (2009); *FCC v. Nat'l Citizens Comm. for Broad.*, 436 U.S. 775, 814 (1978).

4. Plaintiffs further argue that Defendants failed to consider alternative options. On the contrary, the agency did consider alternatives proposed by commenters. *See* Britton Decl. ¶ 21. For example, HRSA rejected alternatives like the Medicare Transaction Facilitator because that methodology does not test the concept of a rebate model, and testing that model to effectuate the 340B ceiling price was the agency's chief aim. *See id.* And there is no clear legal authority in the 340B statute for those alternatives. Moreover, HRSA considered and rejected proposals to further limit the scope of the Pilot to a smaller subset of drugs. Only a very small percentage of drugs are currently included in the Pilot Program and further restricting that number would interfere with the agency's ability to collect sufficient information on which to evaluate the viability of a broader rebate model. *See* Britton Decl. ¶ 22–23.

HRSA likewise considered commenters' suggestions to limit the Pilot Program to a subset of covered entities or only to covered entities that volunteered to participate. The 340B Program contains a wide variety of covered entity types, ranging from federally qualified health centers, certain children's hospitals and free-standing cancer hospitals, critical access hospitals, rural referral centers, black lung

clinics, and other federally funded health care entities. 42 U.S.C. § 256b(a)(4). HRSA did not limit the Pilot Program to a subset of those covered entities because it was important to the agency that manufacturers be able to structure their rebate programs to test the model for as broad a variety of covered entities as possible. *See* Britton Decl. ¶ 24.

5. Finally, Plaintiffs assert that the agency improperly sought a predetermined result. But they offer no support for that allegation, much less the support needed to overcome the presumption of regularity afforded agency action. *See United States v. Chem. Found., Inc.*, 272 U.S. 1, 14–15 (1926) ("The presumption of regularity supports the official acts of public officers, and . . . that they have properly discharged their official duties."). Indeed, the initiation of a Pilot Program does not conclusively determine anything. It is meant to "better understand the merits and shortcomings of the rebate model from stakeholders' perspectives, and to inform [agency] consideration of any future 340B rebate models." 90 Fed. Reg. at 38,165. In any event, the APA does not impose "an open-mindedness test." *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657, 685 (2020).

For these reasons, Plaintiffs' arbitrary and capricious claim should fail.

II. Plaintiffs Have Failed to Show Irreparable Harm

Plaintiffs must also show that a preliminary injunction is needed "to prevent a real threat of [irreparable] harm." *Matos ex rel. Matos v. Clinton Sch. Dist.*, 367 F.3d 68, 73 (1st Cir. 2004). "A finding of irreparable harm must be grounded on something more than conjecture, surmise, or a party's unsubstantiated fears of what the future may have in store." *Charlesbank Equity Fund II v. Blinds to Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004); *see also Winter*, 555 U.S. at 22 ("[A party] seeking preliminary relief [must] demonstrate that irreparable injury is *likely* in the absence of an injunction"). In other words, "speculative injury" is not enough. *Narragansett Indian Tribe v. Guilbert*, 934 F.2d 4, 6–8 (1st Cir. 1991) (citation modified).

Significantly, Plaintiffs do not claim that the rebate model reduces the amount of their 340B discounts. Nor could they, as that amount is set by the statute and the challenged agency action here merely changes how those discounts are disbursed in a way that is clearly authorized by the 340B

statute. Rather, Plaintiffs principally focus on three theories of harm: 1) increased upfront costs; 2) increased administrative costs; and 3) harm to their missions. None of these asserted harms rises to the level of irreparable harm.

First, with respect to increased upfront costs, Plaintiffs have failed to show that they face irreparable harm from the ten-day period between submitting their claims and receiving their rebates. Although they allege that they do not have significant amounts of cash on hand, they do not explain why a ten-day payment window will cause them irreparable harm, particularly given the limited scope of the Pilot Program and the likelihood that, for most purchases of the ten drugs included in the Pilot Program, covered entities will receive rebates before their payment is due to the wholesaler. *See* Britton Decl. ¶ 30. And while Plaintiffs allege that there could be significant delays between ordering drugs and dispensing them, manufacturers will pay unit-level rebates rather than package-level rebates, so covered entities will not have to wait to dispense an entire package before requesting a rebate. *Id.* ¶ 29. And in any event, most drugs included in the Pilot Program are dispensed as a full package size and do not sit on the shelf for long periods of time. *See id.* ¶ 28. All of these features should mitigate any financial strain on covered entities by minimizing or eliminating the need to wait long periods of time between ordering drugs and requesting rebates.

Plaintiffs also speculate that they'll have to float their capital to drug manufacturers for unknown periods of time "with no enforceable guarantee of repayment," Pls.' Br. at 17. But as explained above, manufacturers are required to ensure that all rebates are paid to the covered entities, or denied with documentation in support, within ten days of data submission. 90 Fed. Reg. at 36,165. And HRSA has limited the grounds on which manufacturers can deny claims and reserves the right to revoke approval of a manufacturer plan at any time if the manufacturer fails to comply with the Pilot Program's criteria. *Id.* at 36,164. Plaintiffs' unsupported fears that manufacturers will fail to "reimburse hospitals within ten days" or "inappropriately deny rebates" are therefore too speculative to support irreparable harm. *See, e.g.*, Decl. of Winfield S. Brown ¶ 20, Doc. No. 5 ("Brown Decl.");

Decl. of Sean M. Fadale ¶ 21, Doc. No. 6 ("Fadale Decl.") ("I am also concerned that the drug companies will not reimburse [Plaintiff] within ten days because Defendants have not set out clear consequences for late or unfairly denied rebates."); Decl. of Alan W. O'Neil ¶ 17, Doc. No. 9 (similar).

Plaintiffs next contend that they face irreparable harm from increased administrative costs. But Plaintiff Maine Hospital Association states only in a vague and conclusory fashion that its members have "serious concerns" about the Pilot Program, including their inability to fund the administrative costs necessary to comply with it. Decl. of Jeffrey Austin ¶ 14, Doc. No. 4. That assertion is not enough to establish standing, much less irreparable harm. *See, e.g.*, *Cacchillo v. Insmed, Inc.*, 638 F.3d 401, 404 (2d Cir. 2011) ("[T]o establish standing for a preliminary injunction, a plaintiff cannot rest on . . . mere allegations, as would be appropriate at the pleading stage." (citation modified)). For their part, Plaintiffs St. Mary's Regional Medical Center and Nathan Littauer Hospital and Nursing Home aver that each will have to hire a new staff person if the program is implemented. *See* Brown Decl. ¶ 21; Fadale Decl. ¶ 22. But neither establishes that those burdens are sufficiently weighty to constitute irreparable harm, especially given the financial benefits that flow to Plaintiffs due to 340B discounts. *See Sierra Club v. Larson*, 769 F. Supp. 420, 422 (D. Mass. 1991) ("To establish irreparable harm there must be an actual, viable, presently existing threat of *serious* harm." (emphasis added)).

Finally, Plaintiffs assert that the Pilot Program will cause irreparable harm to their missions, as they face financial uncertainty and may have to delay maintenance on hospital facilities and cut back on health-promoting services. But these fundamentally economic harms do not threaten the very "survival" of Plaintiffs' businesses, as they must to qualify as irreparable, particularly given the limited scope of the Pilot. *Coastal Cntys. Workforce, Inc. v. LePage*, 284 F. Supp. 3d 32, 59 (D. Me. 2018), *appeal dismissed*, 2018 WL 3440030 (1st Cir. Mar. 2, 2018); *see also Dr. Jose S. Belaval, Inc. v. Perez-Perdomo*, 465 F.3d 33, 36 n.2 (1st Cir. 2006) (explaining that the plaintiff had "filed documents . . . indicating that it was on the brink of financial ruin"). To the extent Plaintiffs attempt to bolster their claims of

irreparable harm by relying on injuries to patients, that fails as well. Plaintiffs may not rely on alleged harms to third parties to demonstrate irreparable harm. The "issuance of a preliminary injunction requires a showing of irreparable harm *to the movant* rather than to one or more third parties." *CMM Cable Rep., Inc. v. Ocean Coast Props., Inc.*, 48 F.3d 618, 622 (1st Cir. 1995); *see also Winter*, 555 U.S. at 20 ("A plaintiff seeking a preliminary injunction must establish . . . that *he* is likely to suffer irreparable harm in the absence of preliminary relief." (emphasis added)). Thus, Plaintiffs have failed to establish irreparable harm.

III. The Balance of Equities and Public Interest Favor the Government

Even if Plaintiffs could establish irreparable harm, they have not shown that "the balance of equities and consideration of the public interest" favor a preliminary injunction. *Id.* at 32. Where, as here, the government is the defendant, these factors "merge." *Nken*, 556 U.S. at 435.

As the First Circuit has recognized, "[a]ny time a [government] is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Dist. 4 Lodge of Int'l Ass'n of Machinists & Aerospace Workers Loc. Lodge 207 v. Raimondo*, 18 F.4th 38, 47 (1st Cir. 2021) (quoting *Maryland v. King*, 567 U.S. 1301, 1303 (2012)). That is particularly true here, where Congress has explicitly granted the Secretary of HHS the authority to choose between rebates or discounts in administering the 340B program. Pursuant to that authority, the agency has decided to test the viability of one of those options in a way designed to limit adverse impacts on covered entities. Moreover, the agency's choice is motivated in part to help regulated parties address deduplication between 340B prices and negotiated prices under the Medicare Drug Price Negotiation Program, where the first set of negotiated prices is set to take effect on January 1. Regulatory agencies "must be given ample latitude to 'adapt their rules and policies to the demands of changing circumstances.'" *State Farm*, 463 U.S. at 42. And while Plaintiffs claim that the balance of the equities and the public interest favor them because there is no public interest in the perpetuation of unlawful agency action, Pls.' Br. at 19, that argument only presupposes the success of their incorrect view of the merits. Accordingly, the balance of equities and public interest favor the Government.

IV. Any Relief Must Be Limited to the Named Plaintiffs and Members the Associational Plaintiffs Have Chosen to Identify for Purposes of Standing[8]

If the Court is inclined to grant Plaintiffs' motion, it should limit any injunction to the named Plaintiffs and the members that the American Hospital Association (AHA) and Maine Hospital Association (MHA) have chosen to identify who have standing.

1. At the outset, this Court cannot grant relief as broadly as Plaintiffs request. Plaintiffs request that this Court prohibit Defendants from implementing the Pilot Program pending a final judgment on the merits, *see id.* at 20, which, apart from being improper for the reasons explained above, *see supra* Argument Section I.A., would extend relief to covered entities who are neither parties to this litigation nor members of the associational Plaintiffs. But as the Supreme Court recently made clear, federal courts are not authorized to issue universal injunctions—injunctions that extend relief beyond the parties to the litigation. *Trump v. CASA, Inc.*, 606 U.S. 831, 856 (2025).

Traditionally, "when a federal court finds a remedy merited, it provides party-specific relief, directing the defendant to take or not take some action relative to the plaintiff." *United States v. Texas*, 599 U.S. 670, 693 (2023) (Gorsuch, J., concurring). That practice comports with the "founding-era understanding that courts 'render a judgment or decree upon the right of the litigant[s]." *Id.* (citation omitted) (Gorsuch, J., concurring). Relief drawn in this way ensures that federal courts respect the limits of their authority under Article III "to decide cases and controversies and avoid trenching on the power of the elected branches to shape legal rights and duties more broadly." *Id.* at 694; *see also Doran v. Salem Inn, Inc.*, 422 U.S. 922, 931 (1975) ("[N]either declaratory nor injunctive relief can directly interfere with enforcement of contested statutes or ordinances except with respect to the particular federal plaintiffs.").

Accordingly, any equitable remedy should apply only to the named parties. *See California v. Texas*, 593 U.S. 659, 672 (2021) (remedies "ordinarily operate with respect to specific parties" rather

[8] The Court has asked the parties to address whether the American Hospital Association (AHA) has associational standing. Defendants do not contest that the AHA has standing to seek relief on behalf of its members. *See Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977).

than "on legal rules in the abstract" (citations omitted)); *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (observing that the "general rule" is that equitable relief "should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs" (citation omitted)).

2. In the context of associational plaintiffs, this means that relief should extend only to the members that the associations have chosen to identify and for whom the associations have established standing. That latter showing would entail, for example, establishing not only that the member participates in the 340B program but also that it administers a drug that has been approved for a rebate model and would face irreparable harm absent preliminary relief. *See Summers v. Earth Island Inst.*, 555 U.S. 488, 499–500 (2009) ("[T]he Court has required plaintiffs claiming an organizational standing to identify members who have suffered the requisite harm.").

Limiting a remedy to the members the associational plaintiffs have identified for standing purposes comports with the limitations on extending relief to nonparties outlined above. *See CASA*, 606 U.S. at 856. This Court cannot circumvent that prohibition indirectly by extending relief to nonparties who are represented by a party, other than through properly established associational standing or class certification under Rule 23. *See Smith v. Bayer Corp.*, 564 U.S. 299, 315 (2011) ("[A] properly conducted class action . . . can come about in federal courts in just one way—through the procedure set out in Rule 23."). Neither associational Plaintiff has sought or obtained class certification, and the AHA has identified just four of its thousands of members for standing purposes. *See* Compl. ¶ 13. For its part, the MHA has identified only one member. *See id.* ¶ 14. The AHA and MHA cannot end-run all three of those limits—*CASA*, Rule 23, and associational standing requirements—by obtaining an injunction barring the Government from effectuating 340B pricing through rebates for members whose membership is unknown.

Limiting the remedy in this way also appropriately leaves the breadth of the remedy those plaintiffs can receive in their own hands. Nothing prevents the AHA or the MHA from naming as

many of its members as it wishes so that each member can benefit from any relief the Court orders. Likewise, nothing prevents those Plaintiffs' members from seeking to litigate this case as a class action. Thus, any remedy should only extend to cover the specific identified members for which the associations have shown irreparable harm, and should be tailored only to address the irreparable harms shown by those specific members.

V. Any Relief Should Be Accompanied by a Bond

Defendants also respectfully request that any injunctive relief be accompanied by a bond under Federal Rule of Civil Procedure 65(c), which provides that "[t]he court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained."

CONCLUSION

For the foregoing reasons, this Court should deny Plaintiffs' motion for a preliminary injunction.

Dated: December 15, 2025

Respectfully submitted,

YAAKOV M. ROTH
Principal Deputy Assistant Attorney General
Civil Division

MICHELLE R. BENNETT
Assistant Director
Federal Programs Branch

/s/ Elisabeth J. Neylan
Elisabeth J. Neylan
Trial Attorney (N.Y. Bar Reg. No. 6125736)
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L St. NW
Washington, DC 20005
Tel: (202) 616-3519; Fax: (202) 616-8460
E-mail: Elisabeth.J.Neylan@usdoj.gov

Attorneys for Defendants

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, et al, Plaintiffs, v. ROBERT F. KENNEDY, JR. Secretary of the U.S. Department of Health and Human Services, et al., Defendants.	Case No. 2:25-cv-00600-LEW **DECLARATION OF CHAD GOLDER IN FURTHER 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 as a supplement to my declaration executed on November 26, 2025 (ECF Doc. 7), in further support of Plaintiffs' motion for a temporary restraining order or preliminary injunction. The facts in this declaration are based on my personal knowledge and experience, and my review of the AHA's business records.

<u>Walgreens and Walmart</u>

2. I understand from 340B program-participating members of the AHA that work with Walgreens and/or Walmart to assist in distributing drugs to patients that both Walgreens and Walmart have decided that they will exclude the drugs approved for the Rebate Program as of January 1, 2026, from their 340B programs. This means that 340B providers that cannot afford to pay the full wholesale acquisition cost (without any discount or rebate) for Imbruvica, Enbrel, Farxiga, Jardiance, Eliquis, Xarelto, Stelara, Januvia, and Novolog/Fiasp will no longer be able to

use Walgreens' or Walmart's pharmacies as a means of dispensing these prescription drugs to patients.

3. Walgreens informed 340B providers that it was implementing this exclusion because it needs more time to prepare its systems to participate in the Rebate Program, but it did not specify how much additional time it needs.

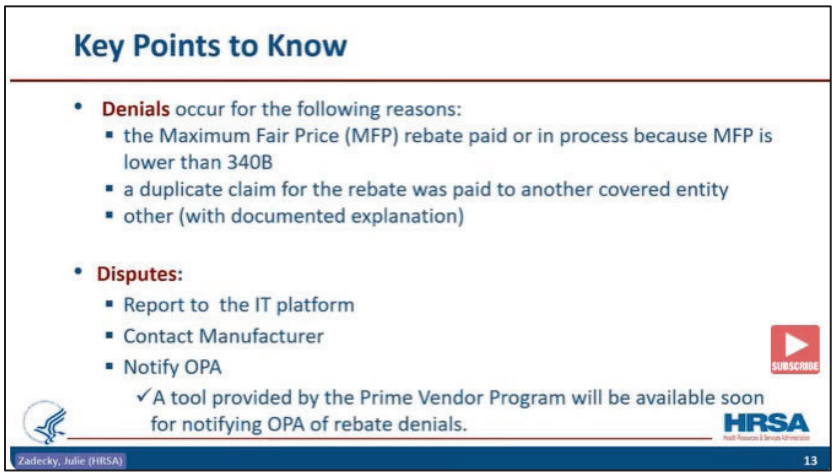
4. Walmart provided that it will block all MFP drugs dispensed to patients under Medicare Part D from inclusion under covered entities' 340B Pharmacy Services Agreement with Walmart, effective January 1, 2026. Walmart identified the "new reimbursement mechanism" and "operational constraints" as motivating its exclusion and did not indicate that its exclusion was temporary.

5. Without partnerships from community pharmacies like Walgreens and Walmart that distribute drugs to 340B hospitals' patients on an outpatient basis, it will be more difficult for patients to obtain the Rebate Program drugs closer to where they live, which is especially important for rural populations. These exclusions also increase the administrative burden of Rebate Program participation on covered entities.

Continued Problems With Beacon Software Platform

6. AHA's members themselves also continue to face difficulty preparing their systems to participate in the Rebate Program, as Beacon has continued to change the parameters of what it will consider acceptable information to validate a rebate claim well past November 2, 2025 (the cut off to provide covered entities with 60 days of notice before January 1). As one AHA member hospital informed me, "[w]e're trying to build" our internal software to meet the acceptable criteria for the Beacon platform, "and the goal post keeps moving."

7. Defendant HRSA admitted in a brief webinar it held for covered entities on December 4, 2025, that drug companies can deny rebate claims for "other" reasons besides the Maximum Fair Price rebate already being paid or in process (where the Maximum Fair Price is lower than the 340B price) or a duplicate claim for the rebate having been paid to another covered entity. Though HRSA's presentation indicated that drug companies are to provide "documented explanation" for such "other" denials, HRSA has not specified what information or detail this explanation must contain, let alone what 340B hospitals can do to appeal to HRSA when they dispute a denial for that "other" reason (or, for that matter, any reason).



See 340B Webinar 12-4-2025, at 12:30, https://www.youtube.com/watch?v=Iw0kxqi74PE.

8. I have been informed by multiple AHA members that Beacon will not complete data security questionnaires or allow standard vendor assessments related to the security of the data that hospitals are required to submit under the Rebate Program. Hospitals complete these security assessments to comply with HIPAA Security Rule (45 CFR § 164.308), which provides that covered entities must "conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity or business associate," and further provides that hospitals

"may permit a business associate to create, receive, maintain, or transmit electronic protected health information on the covered entity's behalf only if the covered entity obtains satisfactory assurances . . . that the business associate will appropriately safeguard the information." Because Beacon is refusing to provide this data security information to the AHA's 340B members, and because Defendants have taken the position that HHS "has no legal authority over Beacon" and "cannot compel Beacon to act in a certain manner," *see* Britton Declaration ¶ 44, Beacon is forcing them to either forfeit access to 340B discounts for the drugs included in the Rebate Program or risk violating HIPAA and other data privacy laws. Notably, contrary to HHS's assertion, *see id*., federal and state data privacy laws provide little protection here because *hospitals* are responsible for their own compliance with HIPAA, and Beacon is making it more difficult for (or preventing) them to do so.

9. Between Walmart and Walgreens pharmacies refusing to participate in the Rebate Program come January 1, continuing shifts in the information covered entities must provide to have their rebate claims validated by Beacon, the opportunity for drug companies to deny rebates for "other" reasons not enumerated by Defendants (still without any defined HRSA dispute resolution process), and continued data security concerns about the Beacon platform that put 340B hospitals at risk of violating their obligations under HIPAA, the AHA's members face an imminent threat of not only incurring administrative costs and delays in accessing 340B savings, but losing those savings altogether for drugs in the Rebate Program.

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

Executed this 18th day of December, 2025 at Washington, D.C.

DocuSigned by:
Chad Golder
3086849272D248B...

Chad Golder

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. ROBERT F. KENNEDY, JR. SECRETARY of the U.S. Department of Health and Human Services, *et al.*, Defendants.	No. 2:25-cv-600-LEW

DECLARATION OF CHANTELLE BRITTON

I, Chantelle Britton, M.P.A., M.S., declare as follows pursuant to 28 U.S.C. § 1746:

1. I am the Director of the Office of Pharmacy Affairs (OPA). OPA is part of the Health Resources and Services Administration (HRSA), an agency within the U.S. Department of Health and Human Services (HHS). OPA has delegated authority to administer the 340B Program, which is codified in statute at 42 U.S.C. § 256b or Section 340B of the Public Health Service Act. OPA is responsible for the day-to-day administration of the 340B Program. I make this declaration based on personal knowledge and information provided to me by my staff in the course of my official duties as the Director of OPA.

Exhibits

2. Exhibit 1 is a true and accurate copy of the documents related to HRSA's approval of AbbVie's submitted plan for the 340B Rebate Model Pilot Program. These documents include AbbVie's initial application (Exhibit 1 0015 – 0026), HRSA's request for revisions and clarifications (Exhibit 1 0031 – 0032), AbbVie's revised application (Exhibit 1 0061 – 0071), HRSA's approval (Exhibit 1 0090 – 0092), and correspondence between HRSA and AbbVie during the approval process.

3. Exhibit 2 is a true and accurate copy of the documents related to HRSA's approval of Johnson & Johnson's submitted plan for the 340B Rebate Model Pilot Program. These documents include Johnson & Johnson's initial application (Exhibit 2 0003 – 0009), HRSA's request for revisions and clarifications (Exhibit 2 0025 – 0026), Johnson & Johnson's revised application (Exhibit 2 0066 – 0074), HRSA's approval (Exhibit 2 0085 – 0087), and correspondence between HRSA and Johnson & Johnson during the approval process.

Preliminary Administrative Record Index

4. HRSA is in the process of compiling the administrative record for this case. I certify that the Administrative Record includes, but is not limited to, the exhibits listed above and the documents that are listed in the index below. I note that this list is not comprehensive and that HRSA has not been able to determine the total page count for many of the documents because HRSA is still compiling the Administrative Record:

a. Press Release, HRSA, HRSA Announces Application Process for the 340B Rebate Model Pilot Program and Request for Public Comment (July 31, 2025), https://www.hrsa.gov/about/news/press-releases/rebate-model-pilot-program ("HRSA Press Release")

b. 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program, 90 Fed. Reg. 36,163 (Aug. 1, 2025)

c. 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program; Correction, 90 Fed. Reg. 38,165 (Aug. 7, 2025)

d. HRSA, 340B Drug Pricing Program, FAQs, https://www.hrsa.gov/opa/faqs?categories=All&keywords= (last visited Dec. 21, 2025)

e. Comments received in response to the Notice

f. Applications to participate in the 340B Rebate Model Pilot Program

g. Correspondence between HRSA and manufacturers regarding the applications

h. Letters approving applications

In accordance with 28 U.S.C. § 1746, I declare, under penalty of perjury, that the above information is true and correct to the best of my knowledge and belief.

Signed this 22nd day of December 2025.

Chantelle V. Britton -S

Digitally signed by Chantelle V. Britton -S
Date: 2025.12.22 13:00:59 -05'00'

Chantelle Britton, M.P.A., M.S.
Director
Office of Pharmacy Affairs
Health Resources and Services Administration

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, ET AL., Defendants.	Case No. **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

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, ET AL., Defendants.	Case No. **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

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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.

<u>/s/ Sean M. Fadale</u>

Sean M. Fadale

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, ET AL., Defendants.	Case No. **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, Plaintiffs, v. ROBERT F. KENNEDY, JR. Secretary of the U.S. Department of Health and Human Services, ET AL., Defendants.	Case No. **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.

<u>/s/ Alan W. O'Neil</u>

Alan W. O'Neil