

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE**

THE AMERICAN HOSPITAL
ASSOCIATION, THE MAINE HOSPITAL
ASSOCIATION, EASTERN MAINE
MEDICAL CENTER, NATHAN LITTAUER
HOSPITAL & NURSING HOME, UNITY
MEDICAL CENTER, and DALLAS
COUNTY MEDICAL CENTER,

Plaintiffs,

v.

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

Defendants.

Case No.:

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

EXPEDITED CONSIDERATION AND ORAL ARGUMENT REQUESTED

INTRODUCTION

Ten months ago, this Court enjoined Defendants’ attempt to introduce an unprecedented rebate mechanism into the 340B Program. Unchastened, Defendants have returned with a “340B Rebate Model Pilot Program” (Rebate Program) that is nearly twice as large. But just like before, Defendants “failed to follow the APA’s basic blueprint.” *Am. Hosp. Ass’n v. Kennedy*, 820 F. Supp. 3d 30, 47 (D. Me. 2025) (*AHA I*). Immediate judicial intervention is necessary to protect the “financial survival” of 340B hospitals and the health of their patients. *Am. Hosp. Ass’n v. Kennedy*, 164 F.4th 28, 33–34 (1st Cir. 2026) (*AHA II*).

Defendants have again violated the APA in multiple ways. Like last year, they “failed to consider an important aspect of the problem”—“the costs and benefits associated with the regulation.” *AHA I*, 820 F. Supp. 3d at 44. They err on *both sides* of the cost-benefit equation by “unreasonably understat[ing] the costs of the [Rebate Program] while unreasonably overstat[ing] the benefits.” *Chamber of Com. of the U.S. v. FTC*, 820 F. Supp. 3d 473, 491 (E.D. Tex. 2026).

On the cost side, Defendants’ analysis “was egregiously flawed and incomplete.” *Presidents’ All. on Higher Educ. & Immigr. v. DHS*, 2026 WL 2690098, at *15 (D. Mass. Sept. 14, 2026). They estimate that covered entities will spend over \$537 million annually if their Rebate Program takes effect. That number is astonishing, but the reality is even worse. Their own half-billion-dollar figure runs counter to overwhelming record evidence (based on first-hand information submitted by 340B hospitals and other covered entities) showing that data-submission costs will require far more work than Defendants predict. Worse still, Defendants arbitrarily excluded *entire categories* of administrative costs. For example, Defendants disregarded backend reconciliation of paid and denied rebates—the costliest operational burden of a rebate mechanism. They completely wrote off startup, vendor, and training costs, even though they admit these costs

will occur. They entirely dismiss “float[] costs” (*i.e.*, having to provide “an interest-free loan from the hospitals to” drug companies, *AHA II*, 164 F.4th at 32) based on two drug-industry funded studies that concededly do not address the full scope of those costs. And they wholly discount harms to patients and communities, even though this Court previously held that spending hundreds of millions of dollars on administrative costs will have the “downstream effect [of] causing [hospitals] to cut back services.” *AHA I*, 820 F. Supp. 3d at 46.

On the benefits side, Defendants’ errors are just as fatal. They never quantified the scope of the purported duplicate discount problem they claim to solve. They never evaluated how the Program will *incrementally* solve that purported duplicate discount problem. And they unquestioningly accepted predictions from drug companies about the purported benefits of a rebate mechanism, even though the drug companies’ figures contradict Defendants’ own audits and arithmetic. *See* Compl. ¶¶ 18–20, 138–41, 255–57.

Other errors abound. Defendants dismissed “reliance interests” as unjustified as a matter of law only months after conceding they were “significant.” *AHA II*, 164 F.4th at 33. They rejected less burdensome alternatives on unreasonable, speculative, and circular grounds. Most fundamentally, they did not apply the correct legal standard—what payment mechanism is “the most effective and most efficient from the standpoint of each type of ‘covered entity,’” H.R. Rep. No. 102-384, pt. 2, at 16 (1992). Defendants therefore leave the Rebate Program “unmoored from the purposes and concerns” of the relevant law. *Judulang v. Holder*, 565 U.S. 42, 64 (2011).

To be clear, Plaintiffs are not “asking for a policy judgment against the Agency.” *AHA I*, 820 F. Supp. 3d at 45. They ask only for a ruling that Defendants, in making *their own* policy judgment, failed to consider the “right stuff.” 33 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 8415 (2d ed. 2018). After all, “to pass muster under the APA’s ‘arbitrary

and capricious’ test, courts must ‘ensure that agency decisions are founded on a reasoned evaluation of the relevant factors.’” *Penobscot Air Servs., Ltd. v. FAA*, 164 F.3d 713, 719 (1st Cir. 1999) (quoting *Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 378 (1989)). Because Defendants did not do that here, Plaintiffs are likely to succeed on the merits. And because irreparable harm is even more acute than last year and the balance of equities still weighs in Plaintiffs’ favor, this Court should enjoin the new Rebate Program before it goes into effect on January 1, 2027.

BACKGROUND

Congress created the 340B Program so safety-net providers could buy drugs at discounts and “stretch scarce Federal resources as far as possible.” H.R. Rep. No. 102-384, pt. 2, at 12; *see* 42 U.S.C. § 256b. Congress charged the Health Resources and Services Administration (HRSA) with implementing discounts through the payment mechanism “that is the most effective and most efficient from the standpoint of each type of ‘covered entity.’” H.R. Rep. No. 102-384, pt. 2, at 16; *see Novartis Pharms. Corp. v. Kennedy*, 182 F.4th 1027, 1030–31, 1035 (D.C. Cir. 2026). For the past 33 years, HRSA has concluded that a rebate mechanism is “both inferior to Section 340B’s current upfront-discount model and disruptive to safety-net hospitals.” *AHA II*, 164 F.4th at 32.¹

In 2025, however, HRSA attempted to compel more than 14,000 rural and safety-net providers to participate in a so-called “pilot” rebate program. This Court enjoined that program. The First Circuit denied a stay, and the government agreed to vacatur. Compl. ¶¶ 58–64.

Just one week after this Court vacated the program, Defendants set about reviving it. *Id.* ¶¶ 65–69. The new Rebate Program is nearly identical to the one this Court enjoined, only now with 25 potential drugs instead of 10. *See* Notice Regarding 340B Rebate Model Pilot Program,

¹ HRSA had approved a rebate exactly once—for AIDS Drug Assistance Programs, whose purchasing systems “prevented their participation in the section 340B discount program,” and only after finding the change benefited those particular covered entities. 62 Fed. Reg. 45,823, 45,824 (Aug. 29, 1997); 63 Fed. Reg. 35,239, 35,241 (June 29, 1998).

91 Fed. Reg. 48,883 (Aug. 3, 2026) (“Notice”). HRSA has already approved plans for 18 drugs. Compl. ¶¶ 195–201. As before, covered entities must float the full purchase price of 340B drugs to manufacturers, submit claims-level data, and await a rebate.

LEGAL STANDARD AND REVIEWABILITY

A district court may grant a temporary restraining order when a movant shows “(1) it is likely to succeed on the merits; (2) it is likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in its favor; and (4) an injunction is in the public interest.” *Doe v. Trump*, 157 F.4th 36, 46 (1st Cir. 2025). Preliminary relief “preserve[s] the relative positions of the parties until a trial on the merits can be held.” *Starbucks Corp. v. McKinney*, 602 U.S. 339, 346 (2024). The APA separately allows the Court, “to the extent necessary to prevent irreparable injury,” to “postpone the effective date of an agency action” pending review. 5 U.S.C. § 705.

Agency action is arbitrary and capricious when the agency “relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, [or] offered an explanation . . . that runs counter to the evidence before the agency.” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). An agency’s post-remand explanation “‘must be viewed critically’ to ensure that the [action] is not upheld on the basis of impermissible ‘post hoc rationalization.’” *DHS v. Regents of the Univ. of Cal.*, 591 U.S. 1, 21–23 (2020); *Greyhound Corp. v. ICC*, 668 F.2d 1354, 1358 (D.C. Cir. 1981).

ARGUMENT

I. Plaintiffs Are Likely to Succeed on the Merits.

A. HRSA Failed to Apply the Legal Standards That Congress Supplied.

Agency action must rest on “consideration of the relevant factors,” *State Farm*, 463 U.S. at 43, and be “connected to the purpose and concerns of relevant law,” *Gulluni v. Levy*, 85 F.4th

76, 82 (1st Cir. 2023) (citing *Judulang*, 565 U.S. at 64). Here, Congress directed the Secretary, when deciding between upfront discounts and rebates, to “use the mechanism that is the most effective and most efficient *from the standpoint of each type of ‘covered entity.’*” H.R. Rep. No. 102-384, pt. 2, at 16 (emphasis added).² The D.C. Circuit underscored that congressional instruction days before HRSA issued the Notice. *Novartis*, 182 F.4th at 1030–31, 1035. HRSA applied the “standpoint” standard the only time it has approved a rebate mechanism. Compl. ¶¶ 51, 219. Defendants endorsed the “standpoint” standard in recent legal filings. *Id.* ¶¶ 24, 56. Commenters cited this standard and urged HRSA to address it. *Id.* ¶¶ 122, 218; Golder Decl. ¶¶ 17, 54. And the Notice quotes the “standpoint” standard in full. 91 Fed. Reg. at 48,884–85.

But Defendants failed to apply the “standpoint” standard here. The Notice instead announced that HRSA “must balance covered entities’ longstanding reliance on the upfront discount model against the need to ensure effective program oversight, safeguard the benefits of 340B pricing, and maintain program integrity.” *Id.* at 48,887–88. That is clear-cut legal error.

Separately, the Rebate Program is “unmoored” from the *overall* “purposes and concerns” of the 340B statute. *Judulang*, 565 U.S. at 64; *see also Marasco & Nesselbush, LLP v. Collins*, 6 F.4th 150, 172–75 (1st Cir. 2021) (agency action that “frustrates, rather than advances, the statutory mandate” is arbitrary). Forcing covered entities to spend millions of dollars on administrative and “float” costs, even temporarily, means covered entities will reach *fewer* eligible patients and provide *less* comprehensive services. HRSA’s emphasis on program integrity, which this Court has described as a “subsidiary goal[,]” is no answer. *PhRMA v. Frey*, 2026 WL 184504, at *9 n.10 (D. Me. Jan. 23, 2026). By balancing a non-statutory objective against the statute’s

² The First Circuit has relied on committee reports to set the legal limits Congress placed on agency discretion. *See, e.g., Melone v. Coit*, 100 F.4th 21, 33 (1st Cir. 2024); *Grinspoon v. DEA*, 828 F.2d 881, 893–94 (1st Cir. 1987). And Defendants agree that this Committee Report describes the purpose of the 340B statute. *See* 91 Fed. Reg. at 48,899.

undisputed purpose, HRSA “relied on factors which Congress has not intended it to consider.” *State Farm*, 463 U.S. at 43; *see Nat’l Mining Ass’n v. EPA*, 59 F.3d 1351, 1364 (D.C. Cir. 1995); *Georgia v. Brooks-LaSure*, 2022 WL 3581859, at *17–21 (S.D. Ga. Aug. 19, 2022).

B. HRSA Failed to Reasonably Consider the Costs of the Rebate Program.

“A regulation is arbitrary and capricious if the agency failed to consider ... the costs and benefits associated with the regulation.” *AHA I*, 820 F. Supp. 3d at 44; *Michigan v. EPA*, 576 U.S. 743, 752–53 (2015). HRSA made this mistake many times over.

Administrative costs. Defendants estimate that the Rebate Program will impose over \$537 million in costs on covered entities. Compl. ¶¶ 13, 188. While staggering in itself, this number captures only the task of “reporting claims data.” *Id.* ¶¶ 149, 234. But even that figure is unreasonably low. HRSA’s estimate depends on pharmacists spending only 5 hours per week on the Program. *Id.* ¶¶ 67(a), 145. HRSA insists that 5 hours “reflects a reasonable median burden,” 91 Fed. Reg. at 35,990, but never explains where that number came from or the data underlying it.

In reality, that “number appears as if pulled from thin air.” *Am. Fed’n of Gov’t Emps., AFL-CIO v. Trump*, 2026 WL 2677331, at *17 (N.D. Cal. Sept. 11, 2026). The likeliest explanation is that HRSA took its previously unexplained two-hour estimate from 2025 and multiplied it by 2.5, the same factor by which HRSA planned to increase the number of drugs in this year’s Rebate Program. *See* Compl. ¶ 68. In so doing, HRSA never engaged with the first-hand, hospital-level evidence showing that it dramatically undercounted the labor hours needed to submit claims data. *Id.* ¶¶ 73–79, 144–48; *see* Nahoopii Decl. ¶¶ 9, 13; Austin Decl. ¶ 17; Marston Decl. ¶ 20; Fadale Decl. ¶ 23; Denton Decl. ¶ 26; Bertilrud Decl. ¶ 21. “Grappling with relevant data requires more than a mere recitation of unfavorable evidence without further explanation.” *Cigar Ass’n of Am. v. FDA*, 132 F.4th 535, 540 n.2 (D.C. Cir. 2025). “If an agency fails to examine the relevant data—

which examination could reveal, *inter alia*, that the figures being used are erroneous—it has failed to comply with the APA.” *Dist. Hosp. Partners v. Burwell*, 786 F.3d 46, 57 (D.C. Cir. 2015).³

Separately, HRSA acted unreasonably by assigning *no value at all* to every other category of administrative cost. *See Fla. E. Coast Ry., LLC v. Fed. R.R. Admin.*, 186 F.4th 822, 866 (11th Cir. 2026) (An agency “may not simply disregard an entire category of obvious costs.”).

Reconciliation costs. HRSA completely excluded the Rebate Program’s costliest operational feature: tracking and reconciling rebates. *See* Compl. ¶¶ 80–83, 149–54. Covered entity after covered entity told HRSA that this new reconciliation requirement will be the most burdensome, in part because it must be accomplished manually. *Id.* ¶¶ 80–82, 133–34; Nahoopii Decl. ¶¶ 18, 26; Denton Decl. ¶ 28; Marston Decl. ¶ 23; Fadale Decl. ¶ 25; Bertilrud Decl. ¶ 24. HRSA’s irrational and conclusory response was that covered entities “already perform ... reconciliation activities” and that it believes “established technologies” can handle reconciliation. 91 Fed. Reg. at 48,892–94. This misunderstands the new workflow imposed by the Rebate Program. An upfront-discount mechanism pays no rebate, so there is nothing to reconcile on the backend. *See* Compl. ¶¶ 80, 150–51; Golder Decl. ¶ 36. Covered entities will need to stand up new and expensive backend workstreams. Nahoopii Decl. ¶¶ 16–22; Marston Decl. ¶ 23; Fadale Decl. ¶ 26. HRSA nevertheless omitted reconciliation costs despite this overwhelming record evidence.

Startup costs. Commenters identified several high-dollar startup costs that the Rebate Program will force them to absorb, including claims mapping, secure transmission to manufacturers, finance systems redesigned for receivables tracking, training, modified split-billing

³ HRSA’s own conduct confirms the five-hour number was not the product of reasoned analysis. The day *after* publishing the Notice, HRSA filed a Supporting Statement that changed the wage input and produced a different total—\$537,222,270—and recharacterized the same five hours from the “median” burden to the “average” burden, explaining neither change. Compl. ¶¶ 188–89. “Illogic and internal inconsistency [are] characteristic of arbitrary and unreasonable agency action.” *Chamber of Com. of the U.S. v. U.S. Dep’t of Lab.*, 885 F.3d 360, 382 (5th Cir. 2018).

and third-party administrator contracts, and a separate inventory for drugs purchased at WAC. *See* Compl. ¶¶ 88–89, 157; Nahoopii Decl. ¶¶ 10–11.⁴ Although HRSA acknowledged these “legitimate startup activities[,]” it inexplicably excluded them as “transitional.” 91 Fed. Reg. at 48,893. But labeling startup costs as “transitional” merely describes them. It does not evaluate them, much less justify HRSA’s failure to quantify or account for them in its cost-benefit analysis.

Vendor and training costs. Covered entities submitted granular data showing that, separate from data-submission costs, the Rebate Program will impose hundreds of millions of dollars in vendor, software, IT, and audit costs. Compl. ¶¶ 85–87, 156.⁵ HRSA again assigned these costs no value at all because, in its view, “participation in the 340B Program has always entailed some level of compliance and operational cost.” 91 Fed. Reg. at 48,894. But the question under the APA is what *incremental* costs a new program will impose. *See* Compl. ¶¶ 16(a), 156. An agency that does not measure a new program’s cost relative to its existing baseline acts arbitrarily. *Am. Equity Inv. Life Ins. Co. v. SEC*, 613 F.3d 166, 177–79 (D.C. Cir. 2010).

Staffing costs. Hundreds of commenters told HRSA they would need to hire or divert FTEs to handle the Rebate Program’s administrative burdens. *See, e.g.*, Compl. ¶¶ 74–78, 155, 204; *see also* Golder Decl. ¶¶ 18, 37; Austin Decl. ¶ 17; Marston Decl. ¶¶ 20–21; Fadale Decl. ¶ 23; Denton Decl. ¶ 26; Bertilrud Decl. ¶ 21; Nahoopii Decl. ¶ 22. HRSA answered that staffing impacts “will generally be modest,” because additional staffing “may be absorbed within existing operational structures or supported through existing third-party arrangements.” 91 Fed. Reg. at 48,891, 48,893. Defendants once again offer no support for that *ipse dixit*, and they once again never engaged the

⁴ The costs ranged from \$95,000 at a rural Montana hospital, HRSA-2026-0001-0058, to \$3–4 million at the University of Vermont Health Network, HRSA-2026-0001-1720. *See also* Nahoopii Decl. ¶¶ 10–11; Marston Decl. ¶ 18; Denton Decl. ¶ 31; Austin Decl. ¶ 17.

⁵ Their estimates ranged from \$150,000 to more than \$750,000 per hospital annually, which, extrapolated across 2,728 340B hospitals, is more than \$400 million (at the bottom of the range). *See* Compl. ¶¶ 85, 156; Golder Decl. ¶ 19; Austin Decl. ¶ 17; Fadale Decl. ¶ 22; Marston Decl. ¶ 22; Nahoopii Decl. ¶ 22.

contrary real-world evidence submitted by safety-net providers. *See NetCoalition v. SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010) (courts “do not defer to the agency’s conclusory or unsupported suppositions”). Covered entities are “intimately familiar with their budgets and resources” and have “a unique capacity to estimate how” the Rebate Program “would upend their normal practices[.]” *Cath. Legal Immigr. Network, Inc. v. EOIR*, 513 F. Supp. 3d 154, 174 (D.D.C. 2021). HRSA’s unquestioning, data-free response to these individualized assessments of required FTEs is not reasoned decision-making. What’s more, the Notice presumed that the drug companies’ plans would impose consistent requirements, but HRSA’s subsequent approvals belie that assumption and add further confusion, complexity, compliance, and costs. Compl. ¶¶ 198–99.

2. “Float” costs. This Court last year faulted HRSA for its “silen[ce] on the cost of floating the full price of covered drugs until 340B entities receive their rebate.” *AHA I*, 820 F. Supp. 3d at 44–45. The 2026 Notice provides a bit more explanation, but no better reasoning.

HRSA dismissed “float” costs *entirely*, stating that “[it] believes that the Pilot is unlikely to result in unstable cash flow[.]” 91 Fed. Reg. at 48,894. It based this conclusion on two drug-company-commissioned studies: a December 2025 IQVIA paper and a 2021 study by 3 Axis Advisors. Compl. ¶¶ 160–61.⁶ But these self-interested studies do not support Defendants’ conclusion. *See id.* ¶¶ 162–64. IQVIA’s own comment letter concedes that it looked narrowly at the cost of interest under specific (and inaccurate) conditions—it did not consider other “float” costs like prepay deposits, risks to bond covenants, diversion of limited cash-on-hand from payroll and patients, or the impact of delayed rebates. *Id.* ¶ 162. Even worse, IQVIA published a revised paper in April 2026, which *did* identify tens of millions of dollars in interest costs (but still did not

⁶ HRSA cited neither study in the RFI or ICRs, leaving commenters without notice of the key evidence underlying its “float” cost analysis. “[T]he most critical factual material that is used to support the agency’s position” must “be made public in the proceeding and exposed to refutation.” *Air Transp. Ass’n of Am. v. FAA*, 169 F.3d 1, 7 (D.C. Cir. 1999).

address the various other “float” costs). *Id.* ¶ 163. Despite the revised study being published *three months* before the Notice, Defendants cited the *outdated* version without acknowledging it was superseded by data that undermined HRSA’s conclusion. *Id.* ¶¶ 163, 196.⁷ HRSA thus omitted those tens of millions of dollars in interest costs from its cost-benefit analysis. *Id.* ¶¶ 163, 244(b).

Defendants never explained why they cherry-picked these “two relatively unpersuasive studies” over the mountains of evidence from covered entities. *Bus. Roundtable v. SEC*, 647 F.3d 1144, 1151 (D.C. Cir. 2011); *see Window Covering Mfrs. Ass’n v. CPSC*, 82 F.4th 1273, 1291 (D.C. Cir. 2023) (agency may not credit one interested party over hundreds of contrary commenters without explanation). And HRSA’s silence is especially unreasonable because “financial forecasts about what costs the 340B entities can bear for a certain period is not predicated on any specialized or expert knowledge of the Agency.” *AHA I*, 820 F. Supp. 3d at 45. Further, Defendants adopted these studies without addressing their narrow focus and inherent bias, or the criticisms of the studies submitted by other commenters. Compl. ¶¶ 161–62. But agencies cannot “substitute unquestioning reliance on a regulated entity’s submissions for the reasoned analysis the APA requires.” *Cboe Futures Exch., LLC v. SEC*, 77 F.4th 971, 979 (D.C. Cir. 2023) (cleaned up). If HRSA wanted to rely on such studies, “it needed to critically review” those submissions or “perform[] its own comparable analysis.” *Id.*; *Env’t Health Tr. v. FCC*, 9 F.4th 893, 910 (D.C. Cir. 2021) (“While imitation may be the highest form of flattery, it does not meet even the low threshold of reasoned analysis required by the APA[.]”). Defendants did neither.

HRSA likewise erred when it concluded that a 10-day rebate repayment deadline would fix the problem of “float” costs. For starters, commenters explained that many wholesalers require

⁷ The 3 Axis study is just as unsupportive and equally biased. It is five years old and examined only contract-pharmacy entities. Its model also assumed that a month’s drug inventory arrives and is half dispensed on the same day—an assumption that is belied by real-world hospital operations where drugs are continually ordered and dispensed. Compl. ¶ 164. So inapt was the study that Kalderos, the company that paid for it, did not even cite it in its comment letter. *Id.*

payment in 5 to 7 days, not 10, meaning covered entities still need substantial cash reserves to pay the full price of drugs upfront. Compl. ¶¶ 94 & n.3, 208; *see* Golder Decl. ¶¶ 20, 40; Denton Decl. ¶ 21. Other wholesalers commonly demand deposits or prepay escrow accounts, meaning safety-net hospitals will need a permanent cash set-aside to cover the drugs. Compl. ¶ 97. In addition, commenters explained that the 10-day repayment clock does not start until drugs are dispensed, but drugs often sit on shelves for weeks before being dispensed because rural and safety-net hospitals need to stock inventory in case of emergency. *Id.* ¶¶ 95, 169(a). What’s more, the repayment clock does not even start until a complete claim is submitted, and submissions are not instantaneous; claims often cannot be assembled for 30 to 45 days after the medication is dispensed. *Id.* ¶¶ 96, 207; Nahoopii Decl. ¶ 30; *see* Marston Decl. ¶¶ 24, 27. HRSA addressed none of this. But an agency “cannot ignore evidence that undercuts its judgment.” *Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018).

Finally, neither the drug-company studies nor the 10-day deadline account for “**prompt-pay**,” “**cost-of-goods-sold**,” and **other discounts** that covered entities will lose altogether under a Rebate Program. Compl. ¶¶ 104–05, 170; *see also* Golder Decl. ¶ 22; Marston Decl. ¶ 31. This, too, is an entire category of costs that HRSA unreasonably omits from its cost-benefit analysis.

3. Non-economic costs. “[C]ost’ includes more than the expense of complying with regulations,” and extends to “harms that regulation might do to human health.” *Michigan*, 576 U.S. at 752. Last year, this Court recognized that imposing hundreds of millions of dollars in administrative costs will have “the downstream effect [of] causing [hospitals] to cut back services.” *AHA I*, 820 F. Supp. 3d at 46. Although Defendants conceded that this year’s Rebate Program will impose more than a half-billion dollars of administrative costs, Defendants

nonsensically reasoned that the Program will not “materially impair covered entities’ ... ability to furnish services to patients.” 91 Fed. Reg. at 48,899.

This conclusion makes a mockery of the administrative record. Safety-net providers identified concrete threats to patients, including free or discounted drugs that will no longer be provided to uninsured patients, Compl. ¶¶ 107–08; Golder Decl. ¶ 23; Marston Decl. ¶¶ 16, 29; Nahoopii Decl. ¶ 34; Austin Decl. ¶ 10, rural hospitals forced to carry little or no inventory of lifesaving drugs due to cost, Compl. ¶ 109; Denton Decl. ¶¶ 22–23, clinic hours shortened or entire days closed to offset the Rebate Program’s new costs, Compl. ¶ 113(a)–(b), service lines shuttered, *id.* ¶¶ 111–12; Denton Decl. ¶ 33; Austin Decl. ¶ 21; Fadale Decl. ¶¶ 16, 31; Bertilrud Decl. ¶ 29, and more. *See* Compl. ¶¶ 106–13, 171.

Although the Notice briefly gestures toward rural patients who may have to “travel far distances to obtain necessary medications,” 91 Fed. Reg. at 48,898, it does not analyze the Rebate Program’s impact on communities, regions, or facility types. It nowhere addresses, for example, the counties that risk losing their labor-and-delivery, behavioral health, or opioid treatment units. Compl. ¶¶ 111, 211(a)–(b); Austin Decl. ¶¶ 7, 10, 22; Denton Decl. ¶¶ 8, 33. Nor does it address rural patients who face hours of additional travel to get to a facility that stocks their medications or a new hospital they must visit because their local one discontinued vital healthcare services. Compl. ¶¶ 112–13(a); Denton Decl. ¶¶ 8, 13, 33; Fadale Decl. ¶¶ 6, 31; Bertilrud Decl. ¶ 29. Defendants exercise the same “casual indifference to localized impacts” that this Court found unlawful last year. *AHA I*, 820 F. Supp. 3d at 44 n.5. “Even unquantified factors ... cannot be dismissed without further inquiry where their impact is both evident and massively significant.” *Md. People’s Couns. v. FERC*, 761 F.2d 768, 776 (D.C. Cir. 1985) (Scalia, J.).

C. HRSA Failed to Reasonably Consider the Benefits of the Rebate Program.

Agencies may not rely on “illusory” or “unsubstantiated” benefits. *Chamber of Com.*, 820

F. Supp. 3d at 487. But that is exactly what Defendants did here. Their “vague and conclusory assertions about preventing [duplicate discounts] do[] not justify the [Program’s] significant costs.” *Id.* at 489; *see* Compl. ¶¶ 138, 143; Nahoopii Decl. ¶ 31.

HRSA concedes that “there is no federal estimate of the financial extent of duplicate discounts in 340B.” 91 Fed. Reg. at 48,887. Instead, HRSA parrots two figures supplied by the drug industry: a 2019 assertion that such discounts total “as much as \$1.5 billion annually” and a drug company analysis suggesting they could reach “tens of billions of dollars annually.” *Id.* at 48,887, 48,898. HRSA adopted these figures without questioning their veracity, methodology, or self-interested sourcing. *See Susquehanna Int’l Grp., LLP v. SEC*, 866 F.3d 442, 447 (D.C. Cir. 2017) (“unquestioning reliance” on a regulated party’s self-serving submissions is arbitrary); *Cboe Futures Exch.*, 77 F.4th at 979 (same).

HRSA also ignored contrary evidence in its possession. HRSA’s own audit data proves that duplicate discounts have plummeted since 2018, Compl. ¶¶ 140, 253; Golder Decl. ¶ 24, and commenters noted that HRSA found minimal duplicate discounts during its own audits, Compl. ¶ 141. HRSA never addressed these facts. An agency cannot rely on a “clipped view of the record” to support its conclusion. *Lakeland Bus Lines, Inc. v. NLRB*, 347 F.3d 955, 963 (D.C. Cir. 2003).

More fundamentally, HRSA never squares the drug industry’s duplicate discount estimates *for the whole 340B Program* with the fact that the Rebate Program includes only 18 approved drugs. The Notice is quick to point out that a Rebate Program with 25 *drugs* would be less than 5.5% of annual 340B drug sales. 91 Fed. Reg. at 48,893. But it does not apply the same principle to its analysis of the benefits. *See* Compl. ¶¶ 139, 255–57.⁸ That double standard is exactly the

⁸ Using the drug industry’s figure cited by HRSA, 5.5% of \$1.5 billion in alleged duplicate discounts yields \$82.5 million in avoided discounts across the 25 drugs contemplated in HRSA’s RFI. The Rebate Program’s conceded costs alone (\$537 million) thus outstrip that benefit (\$82.5 million) by a ratio of more than 6:1. *See* Compl. ¶¶ 13, 19, 256. The gap is even wider because, as of this filing, the Program covers only 18 approved drugs.

kind of “inconsistent[] and opportunistic[] fram[ing]” that renders a cost-benefit analysis arbitrary. *Bus. Roundtable*, 647 F.3d at 1148–49; *see generally Chamber of Com. of the U.S. v. SEC*, 85 F.4th 760, 778 (5th Cir. 2023) (agency “cannot have it both ways”).

Finally, the Notice never explains how the Rebate Program will prevent duplicate Medicaid discounts. The Notice explicitly bars manufacturers from denying rebates “based on eligibility or compliance concerns with diversion or Medicaid duplicate discounts.” 91 Fed. Reg. at 48,903. So do the 340B statute and decades-old agency guidance. *See* Compl. ¶ 259; Golder Decl. ¶ 25. A drug company therefore must still pay the rebate and later raise Medicaid duplicate discount concerns through the 340B statute’s audit and dispute resolution processes. Compl. ¶¶ 142, 258. This is the same retrospective process drug companies would go through whether they received claims data *before or after* a 340B discount payment. Thus, the Rebate Program generates hundreds of millions of dollars in costs, only to rely on the same preexisting compliance mechanisms for Medicaid duplicate discounts. Imposing exorbitant new costs to achieve no incremental benefits is definitionally unreasonable.

D. HRSA Failed to Reasonably Consider Reliance Interests.

When an agency changes a policy that “has engendered serious reliance interests,” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009), it must “assess [those] reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns,” *Regents*, 591 U.S. at 33. Last year, Defendants “agree[d]” that reliance on 33 years of upfront discounts is “significant,” and both this Court and the First Circuit held that HRSA had failed to appropriately weigh those interests. *AHA I*, 820 F. Supp. 3d at 42–44; *AHA II*, 164 F.4th at 33–34. This year, Defendants arbitrarily reverse course and assert that more than 15,000 safety-net providers were wrong to rely on upfront discounts from the very day the statute was enacted.

In this stunning about-face, the Notice declared that “exclusive reliance on an upfront discount model” was *always* unreasonable because the statute authorizes rebates, so “stakeholders cannot reasonably claim that a rebate model is unforeseeable.” 91 Fed. Reg. at 48,888. But the Supreme Court and the First Circuit have rejected that reasoning. *Regents*, 591 U.S. at 30–33; *Woonasquatucket River Watershed Council v. USDA*, 186 F.4th 25, 46 (1st Cir. 2026).⁹

E. HRSA Ignored Important Problems and Rejected Every Less Burdensome Alternative on Arbitrary Grounds So It Could Reach a Predetermined Result.

Commenters flagged at least three significant problems that will exacerbate the Rebate Program’s costs, burdens, and patient harms. Defendants ignored all of them. *See Ohio v. EPA*, 603 U.S. 279, 298 (2024) (an agency acts arbitrarily and capriciously when it “failed to address an important problem the public could and did raise during the comment period”).

First, commenters noted that federal policies (including the One Big Beautiful Bill Act, Pub. L. No. 119-21) will impose billions of dollars of new costs on covered entities in 2027, just as the Program begins. Caregivers explained that they, their patients, and their communities cannot afford the Rebate Program’s added costs *at this time*. Compl. ¶¶ 114, 174, 283; Golder Decl. ¶¶ 30, 46; Marston Decl. ¶ 14. The Notice said nothing about this important problem.

Second, Defendants offered no dispute resolution procedure, decisionmaker, deadline, or definitive remedy for delayed and denied rebates. They even deferred unveiling compliance “tools” until 30 days *after* the Program begins. 91 Fed. Reg. at 48,895–96. This same “fly[ing] the plane before they build it” approach violated the APA last year. *AHA I*, 820 F. Supp. 3d at 46–47;

⁹ The Notice also argues, without elaboration and in a single conclusory paragraph, that reliance “do[es] not outweigh the significant benefits of proceeding.” 91 Fed. Reg. at 48,889. That statement is a naked *ipse dixit* because, as discussed above, HRSA *never quantified any benefits*. Nor did HRSA discuss the many specific agency actions, over 30-plus years, that caused covered entity reliance. “It is arbitrary and capricious to ignore the facts and circumstances engendered by that prior policy.” *AHA I*, 820 F. Supp. 3d at 42. And at a minimum, this is certainly not the “more detailed justification” required under these circumstances. *Fox*, 556 U.S. at 515.

see Compl. ¶¶ 167–68, 284(b); Golder Decl. ¶¶ 28, 47; Austin Decl. ¶ 19; Marston Decl. ¶ 30 n.6; Fadale Decl. ¶ 21; Denton Decl. ¶ 25; Bertilrud Decl. ¶ 17; Nahoopii Decl. ¶ 20.

Third, commenters identified a range of problems with HRSA’s approved third-party vendor, Second Sight Solutions—including the substantial financial losses that Second Sight’s delays and errors have cost hospitals and other covered entities. The Notice ignored this problem, too. Compl. ¶¶ 132, 186(c), 284(a); Nahoopii Decl. ¶¶ 23–26.

Defendants also unlawfully cast aside several less burdensome alternatives. HRSA’s overarching rationale for rejecting proposed alternatives was that preserving upfront discounts “would not inform whether rebates are an efficient means of effectuating the 340B ceiling price ... and therefore would fail to advance the central purpose of the Pilot.” 91 Fed. Reg. at 48,890. That is to say: alternatives to a rebate mechanism are inadequate because they are not a rebate mechanism. But an agency cannot define its objective as the action itself and then reject every alternative for failing to be that action. *Am. Pub. Health Ass’n v. NIH*, 145 F.4th 39, 54 (1st Cir. 2025) (“circular reasoning” is a “hallmark[] of arbitrary and capricious decision-making”).

The alternatives HRSA specifically addressed were dismissed for equally irrational reasons. Compl. ¶¶ 176–82. For example, HRSA dismissed a neutral data clearinghouse as “not explicitly authorized under the 340B statute,” 91 Fed. Reg. at 48,900, but it included no legal analysis—even though commenters expressly requested that analysis and explained that another HHS agency has built such a clearinghouse. Compl. ¶¶ 119, 176; *see Cigar Ass’n of Am. v. FDA*, 480 F. Supp. 3d 256, 279 (D.D.C. 2020) (agency’s “conclusory assertion that its hands were tied” is arbitrary). HRSA’s other basis for dismissal—that “unlike a clearinghouse, a rebate model by its very nature incentivizes covered entity compliance,” 91 Fed. Reg. at 48,900—is rank speculation, lifted nearly verbatim from a pharmaceutical trade organization’s comment letter, *see*

Compl. ¶ 178; Golder Decl. ¶ 44, contrary to abundant record evidence that covered entities *supported* a clearinghouse alternative, *see* Compl. ¶¶ 119, 179; Golder Decl. ¶ 27; Austin Decl. ¶ 20; Nahoopii Decl. ¶ 32, and belied by the drug companies’ own choices, Golder Decl. ¶ 44.¹⁰

Taken together, the reason for Defendants’ many APA violations is readily apparent: the agency was so committed to a predetermined result that it was “unwilling or unable to rationally consider counterarguments.” *New York v. U.S. Dep’t of Com.*, 351 F. Supp. 3d 502, 663 (S.D.N.Y. 2019), *aff’d in part, rev’d in part on other grounds*, 588 U.S. 752 (2019). Defendants’ post-vacatur conduct bears every hallmark of a predetermined result. HRSA received more than 4,000 submissions across multiple comment periods and changed nothing of substance. Compl. ¶¶ 135–36, 291. It selected its cost figure before receiving a single comment and never moved off it, even as hundreds of comments proved that the figure was wildly off the mark. And it credited drug-company assertions on *every* disputed fact, even though covered entities repeatedly “offered ample basis for the truth of their positions: their extensive knowledge and experience with” hospital operations under the 340B Program. *Cath. Legal Immigr. Network, Inc.*, 513 F. Supp. 3d at 174. When an agency reaches the same result after remand, its actions “must be more than a barren exercise of supplying reasons to support a pre-ordained result.” *Food Mktg. Inst. v. ICC*, 587 F.2d 1285, 1290 (D.C. Cir. 1978); *see Wint v. Yeutter*, 902 F.2d 76, 81 (D.C. Cir. 1990) (where agency on remand “altered its original rationale and arrived at the same result,” “close consideration of the [agency’s] action is warranted”). Defendants’ decision-making cannot survive the most gentle scrutiny, let alone the “critical[]” scrutiny required here. *Regents*, 591 U.S. at 21.

¹⁰ HRSA arbitrarily disposed of the remaining proposed alternatives on similarly flawed grounds. *See* Compl. ¶¶ 180–82, 266–67. It attacked the existing Medicaid Exclusion File rather than commenters’ actual proposal to *enhance* claims modifiers; dismissed “more intensive audits and oversight” as “inherently reactive,” even though the Notice routes all duplicate discount concerns to those same “reactive” audits; rejected a voluntary or narrower pilot on unexamined speculation about “selection bias”; and never addressed prospective publication of the 340B price and MFP, or manufacturer funding of covered entities’ costs. 91 Fed. Reg. at 48,899–901.

II. Plaintiffs Will Suffer Irreparable Harm Absent Preliminary Relief.

Irreparable harm is “a substantial injury that is not accurately measurable or adequately compensable by money damages.” *Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 102 F.3d 12, 19 (1st Cir. 1996). This Court found irreparable harm last year. *AHA I*, 820 F. Supp. 3d at 45–46. Every irreparable harm that existed then exists today—only more so.

Last winter, this Court found irreparable harm because 340B hospitals “estimate[d] \$400 million in compliance costs, the downstream effect [of] causing them to cut back services.” *Id.* at 46. This year, Defendants themselves estimate \$537 million in data-submission costs alone—costs that will, again, force 340B hospitals to cut or eliminate important patient services. Last winter, the First Circuit highlighted the “unrebutted evidence” that many hospitals “operate with less than eleven days’ worth of cash on hand and that the Rebate Program would cause them to lose hundreds of millions of dollars per year that they could not recoup, thus threatening to close several hospitals.” *AHA II*, 164 F.4th at 32. This year, Maine hospitals have a median of 9.3 days’ cash-on-hand, Austin Decl. ¶ 8, making the risk of closure as or more acute. And like before, “because Plaintiffs raise an APA challenge, they cannot recover any damages for the costs incurred from the Rebate Program should it later be invalidated.” *AHA I*, 820 F. Supp. 3d at 46. Plaintiffs and Maine safety-net providers face tens of millions of dollars in unrecoverable costs. *See* Austin Decl. ¶ 17 (approximately \$55 million in annual incremental costs across Maine’s 340B hospitals); Marston Decl. ¶ 20 (EMMC will require two additional analysts at approximately \$123,000 per year); Fadale Decl. ¶ 23 (NLH will need at least one additional FTE, at approximately \$55,000 per year). Plaintiffs’ “inability to recoup those costs in this context demonstrates irreparable harm.” *AHA I*, 820 F. Supp. 3d at 46.

For many safety-net hospitals, these costs will immediately threaten operations. *See, e.g.,*

Nahoopii Decl. ¶¶ 12, 35. In fact, these costs have already forced Plaintiffs and other covered entities to put important projects on hold. *See* Denton Decl. ¶ 34 (DCMC forced to delay critical facility maintenance); Fadale Decl. ¶¶ 29–30 (NLH’s pharmacy build-out on hold due to threat of Rebate Program’s costs); Golder Decl. ¶ 49; Compl. ¶ 212; Bertilrud Decl. ¶ 14 (Rebate Program “would likely remove” Unity’s planned inpatient pharmacy modernization from its capital plan). *See Rhode Island v. Trump*, 781 F. Supp. 3d 25, 52 (D.R.I. 2025) (“halt[ing] services and implement[ing] a hiring freeze” are irreparable harm).

Similarly, both the administrative and “float” costs will threaten bond-covenant defaults, insolvency, diversion of limited cash-on-hand away from payroll and other critical needs, and even participation in the 340B Program itself. Compl. ¶¶ 209, 213; Golder Decl. ¶¶ 48–51; Marston Decl. ¶¶ 16, 18–30; Austin Decl. ¶ 8; Denton Decl. ¶¶ 22–23, 35; Fadale Decl. ¶¶ 19, 31; Bertilrud Decl. ¶¶ 19, 28; Kane-Lewis Decl. ¶¶ 23–24 (the cost of administering a rebate mechanism for DFD Russell “would exceed the entire remaining benefit of the program,” so it “would have to leave the program altogether”).

The Rebate Program’s costs also will prevent Plaintiffs and other covered entities from carrying out their caregiving missions. They directly threaten service line closures and financial assistance programs that reduce the cost of drugs for patients. Denton Decl. ¶¶ 8, 33 (telehealth oncology clinic and intensive outpatient psychiatric program for seniors at risk, in a county with no other mental health counseling); Marston Decl. ¶¶ 16, 29 (Rebate Program could “ultimately forc[e] EMMC to make difficult choices about which services will remain available to our communities”); Austin Decl. ¶ 21 (members would be unable to continue behavioral health, substance use treatment, or labor and delivery services); *see also* Golder Decl. ¶¶ 23, 50; Fadale Decl. ¶¶ 16–17, 31; Bertilrud Decl. ¶ 29; Nahoopii Decl. ¶¶ 34–35. Agency action that forces

regulated parties to divert resources away from their core mission or abandon vital programs causes irreparable harm. *See, e.g., Somerville Pub. Schs. v. McMahon*, 139 F.4th 63, 75 (1st Cir. 2025); *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 9 (D.C. Cir. 2016).

III. The Balance of Equities and the Public Interest Favor Preliminary Relief.

The balance of equities and public interest also support preliminary relief. Plaintiffs and their patients will bear the many harms described above, and the public interest is not served by impairing patient care or access to medications. *See AHA I*, 820 F. Supp. 3d at 46. Meanwhile, there is no public interest in continuing unlawful action. *Somerville Pub. Schs.*, 139 F.4th at 76. “To the contrary, there is a substantial public interest in having governmental agencies abide by the federal laws that govern their ... operations.” *League of Women Voters*, 838 F.3d at 12; *see Maine v. USDA*, 778 F. Supp. 3d 200, 236 (D. Me. 2025); *AHA II*, 164 F.4th at 36–37 (preliminary relief “simply preserves the status quo that has existed for more than three decades”).

IV. No Bond Should Be Required.

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

CONCLUSION

The Court should grant Plaintiffs’ motion and enter an order (1) temporarily enjoining Defendants from implementing the Rebate Program announced at 91 Fed. Reg. 48,883, including by barring approved manufacturer plans from taking effect; (2) postponing the effective date of the Notice and those approvals under 5 U.S.C. § 705; and (3) granting such further relief as is just. Because the Program takes effect January 1, 2027, Plaintiffs request an expedited schedule.

Dated: October 9, 2026

Respectfully submitted,

/s/ Melissa A. Hewey

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION,
THE MAINE HOSPITAL ASSOCIATION,
EASTERN MAINE 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.

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”). Founded in 1898, the AHA leads, represents, and serves nearly 5,000 member hospitals, health systems, and other healthcare organizations, as well as 43,000 individual members, with the mission of advancing the health of all individuals and communities. Through its representation and advocacy, the AHA ensures that its members’ perspectives and needs are heard in national health policy development and in legislative and regulatory debates. 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, my review of the administrative record, information provided to me by our members, 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 Deputy General Counsel.

3. Before joining the AHA, I was a Partner and founding member of Munger, Tolles & 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. 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 and have limited cash-on-hand.

5. I am familiar with the 340B program's longstanding upfront discount mechanism, with Defendants' first attempt to replace that mechanism with a rebate program in 2025, and with Defendants' current plan to replace it with an expanded rebate program beginning January 1, 2027. I submitted comments in opposition to both plans on the AHA's behalf, and I submitted a declaration in support of Plaintiffs' motion for a temporary restraining order in *American Hospital Association v. Kennedy*, 820 F. Supp. 3d 30 (D. Me. 2025). I know the harm that this second rebate program will cause the AHA's members and mission if it is not enjoined before January 1, 2027.

This Court Enjoined Defendants' First Rebate Program, and Defendants Returned With an Expanded One

6. On August 1, 2025, Defendant Health Resources and Services Administration ("HRSA") published a "340B Rebate Model Pilot Program" covering ten drugs and scheduled to begin January 1, 2026. Plaintiffs challenged that program on December 1, 2025. On December

29, 2025, this Court preliminarily enjoined the program, holding that Defendants “failed to follow the APA’s basic blueprint,” showed “casual indifference to localized impacts,” left the record “silent on the cost of floating the full price of covered drugs,” and did not consider covered entities’ reliance interests.¹ The First Circuit denied a stay pending appeal on January 7, 2026, describing the administrative record as “threadbare.”² Defendants then dismissed their own appeal, and on February 10, 2026, this Court vacated the program and remanded to HHS.

7. Seven days after that vacatur, HRSA published a Request for Information asking covered entities to provide the incremental cost data the agency had failed to evaluate the first time—one-time startup costs, ongoing administrative costs, whether a rebate program would require additional full-time employees, what new or modified information technology systems would be needed and at what cost, impacts on cash flow and liquidity, what prompt-pay discounts covered entities would forfeit, and what reductions in services and impacts on patient access would follow.³ HRSA also published two Information Collection Request notices seeking comment on the paperwork burden its program would impose.⁴

8. On August 3, 2026, HRSA published a notice (the “Notice”) announcing a second rebate program (the “Rebate Program” or “Program”), effective immediately, with manufacturer plan approvals due September 24, 2026, and a start date of January 1, 2027.⁵

¹ *Am. Hosp. Ass’n v. Kennedy*, 820 F. Supp. 3d 30, 44–47 & n.5 (D. Me. 2025).

² *Am. Hosp. Ass’n v. Kennedy*, 164 F.4th 28, 34 (1st Cir. 2026).

³ Request for Information: 340B Rebate Model Pilot Program, 91 Fed. Reg. 7,287, 7,290–91 (Feb. 17, 2026) (the “RFI”) (asking about, *inter alia*, “administrative, operational, financial, and medication access concerns in connection with rebate models”; “reliance interests”; “potential cash-flow impacts”; “proposed alternatives and scope-limiting measures to inform a rebate pilot design, including safeguards to promote the integrity of the 340B Program, and avoid duplicate discounts”).

⁴ 91 Fed. Reg. 9,632 (Feb. 26, 2026); 91 Fed. Reg. 35,989 (June 15, 2026).

⁵ 91 Fed. Reg. 48,883, 48,884, 48,902 (Aug. 3, 2026).

9. One day later, on August 4, 2026, HRSA submitted its cost estimate to the Office of Management and Budget.⁶ The following day, August 5, 2026, OMB approved that cost estimate “without change.”⁷

10. On October 1, 2026, HRSA published the rebate plans it had approved for ten manufacturers covering eighteen drugs (the “Approved Plans”).⁸

11. The new Rebate Program is larger than the one this Court enjoined. At this time, it includes eighteen drugs rather than ten. Like before, moreover, the Program reaches all 15,000-plus covered entities, regardless of size, location, or services offered. And it remains a “pilot” only in name: participation is compulsory for covered entities but remains voluntary for drug companies.⁹

The AHA’s Comments on Defendants’ Rebate Program

12. The AHA participated at every stage of the administrative process. I submitted three comment letters to HRSA in 2026 on behalf of the AHA and its more than 2,000 member hospitals and health systems that participate in the 340B program. I adopt and incorporate each of those letters into this declaration.

13. On April 20, 2026, the AHA submitted a fifty-three page comment responding to HRSA’s Request for Information. HRSA-2026-0001-1846 (the “AHA Letter”). That letter explained why a rebate mechanism of any kind is flawed in both conception and design. It urged

⁶ HRSA, Supporting Statement A, 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Control No. 0906-NEW (Aug. 4, 2026) (the “Supporting Statement”), https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202606-0906-001.

⁷ Off. of Info. & Regul. Affs., Off. of Mgmt. & Budget, *OMB Control Number History*, OMB Control No. 0906-0117, <https://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0906-0117> (last visited Sept. 25, 2026).

⁸ HRSA, *340B Rebate Model Pilot Program*, <https://www.hrsa.gov/opa/340b-model-pilot-program> (last visited Oct. 6, 2026).

⁹ 91 Fed. Reg. at 48,900 n.32.

HRSA to abandon the idea altogether, while also proposing alternatives for the agency to consider. It also incorporated each of the AHA's prior comment letters on the 2025 rebate program.¹⁰

14. On April 27, 2026, the AHA submitted a comment responding to HRSA's February 26 Information Collection Request (the "AHA April ICR Comment").¹¹ That letter reiterated that HRSA's estimated burden was "wildly off-the-mark"; that significant amounts of manual labor would be required because automated tools cannot eliminate the administrative burdens; and that the costs extend well beyond labor hours to include payments to outside vendors, the cost of floating millions of dollars to drug companies as zero-interest loans, and non-economic costs to patients and communities. Ex. 1 to the Complaint at 31.

15. On July 15, 2026, the AHA submitted a comment responding to HRSA's June 15 Information Collection Request (the "AHA July ICR Comment").¹² That letter set out eight specific defects in HRSA's five-hour-per-week claims-submission estimate and asked the agency to explain, in numbers rather than adjectives, how it arrived at that figure—including which below-five-hour estimates in the record could possibly offset the many above-five-hour estimates submitted by hospitals, and why a "median" was the right measure. Ex. 1 at 24–29.

Issues Raised in the AHA's Comments

16. Because I adopt those letters in full, I summarize here only the principal issues the AHA's letters collectively raised.

¹⁰ See AHA Letter at 1 n.1; HRSA-2025-0001-0052; HRSA-2025-0001-0005; 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>.

¹¹ Letter from Chad Golder, Gen. Counsel & Sec'y, Am. Hosp. Ass'n, to HRSA Information Collection Clearance Officer (Apr. 27, 2026) (responding to 91 Fed. Reg. 9,632 (Feb. 26, 2026)), Ex. 1 at 31–32.

¹² Letter from Chad Golder, Gen. Counsel & Sec'y, Am. Hosp. Ass'n, to Thomas J. Engels, Adm'r, Health Res. & Servs. Admin. (July 15, 2026) (responding to 91 Fed. Reg. 35,989 (June 15, 2026)), Ex. 1 at 24–30.

17. **The legal standard for determining the appropriate payment mechanism.**

HRSA's RFI sought input on how to "appropriately balance stakeholder concerns regarding implementation of a rebate model against the agency's goal of testing rebates in the 340B Program[.]"¹³ The AHA's comment letter explained that this was the incorrect legal standard. Specifically, it told HRSA that "*it must give primacy to covered entities on this issue, see H.R. Rep. 102-384, pt. 2, at 16 (1992).*" AHA Letter at 3. As a result, the AHA explained, HRSA's balancing approach "fails from the start." *Id.*

18. **Administrative costs.** The AHA explained that a rebate program would impose far more cost on 340B hospitals than HRSA estimated. AHA Letter at 5–32. HRSA's own figure—\$537 million annually—covers a single task, submitting claims data.¹⁴ Applying HRSA's own labor inputs, the AHA showed that if a rebate program requires each 340B hospital to add even one full-time employee working forty hours per week—an estimate our members consider conservative—the labor cost will be roughly \$750 million a year for 340B hospitals alone. Even that figure, the AHA told HRSA, understates the burden, because it omits the roughly 11,900 covered entities that are not hospitals. AHA Letter at 6–9.

19. **Excluded categories of costs.** The AHA also explained that HRSA's cost estimate excludes entire categories of operational costs, including the one that our members expect to be the largest: back-end reconciliation. Under a rebate mechanism, our members will need to match paid rebates to submitted claims, investigate shortfalls, and pursue missing and denied rebates—an entire workstream that does not exist under the upfront discount our members use today. The AHA explained, based on extensive input from our members, that this reconciliation work cannot be automated. It must be done manually. *Id.* at 14–15. HRSA's cost

¹³ 91 Fed. Reg. at 7,289.

¹⁴ Supporting Statement at 11.

estimate also excludes third-party administrator and vendor fees, information technology support, and financial audit costs, which our members reported at \$150,000 to more than \$750,000 per hospital each year. *Id.* at 9–11. It also omits training. And it omits one-time startup costs, which my conversations with members and review of the administrative record place at tens of thousands of dollars for the smallest facilities and three to four million dollars for large academic systems. If you take an extraordinarily conservative estimate of \$150,000 per hospital for these ignored costs and extrapolate it across the 2,728 340B hospitals, the total comes to more than \$400 million a year. Add the roughly \$750 million a year in labor from just one additional full-time employee per hospital, and administrative costs exceed \$1 billion annually for 340B hospitals alone—and several billion dollars a year across all covered entities. *Id.* at 11. Again, that estimate was based on conservative assessments of administrative costs.

20. **“Float” costs.** The AHA explained that a rebate mechanism forces our member hospitals to front the wholesale acquisition cost of every covered drug and then wait to be repaid—an arrangement the First Circuit described as “essentially functioning as an interest-free loan from the hospitals to the manufacturers.”¹⁵ The AHA told HRSA that its assumptions about the timing of this “float” were incorrect. For example, we explained that wholesaler payment terms are frequently five or seven days, not the ten HRSA assumed. We explained that drugs often are not dispensed before the wholesaler’s invoice comes due. We explained that some wholesalers require multi-million-dollar prepaid escrow accounts regardless of when a rebate arrives. And we explained that facilities operating on a handful of days of cash-on-hand could breach bond and debt covenants before rebates arrived. AHA Letter at 18–29.

¹⁵ *Am. Hosp. Ass’n*, 164 F.4th at 32.

21. **Covered entities' experience with other rebate mechanisms.** The AHA described problems that covered entities have had with other programs conducted by these same drug companies and vendor technologies, including the vendor (Second Sight Solutions) that was chosen to operate the Rebate Program. The record showed that, under the Maximum Fair Price refund process and the Medicare Drug Price Negotiation Program, payments are routinely late; that one academic health system identified at least 100 misclassified claims and approximately \$178,000 in erroneously denied refunds in the first two months of that program; that one rural system saw twenty-three of forty-two qualifying dispenses processed incorrectly in a single month, twenty-two of which it proved were in fact 340B drugs; and that each contested claim takes up to thirty minutes of staff time to resolve through a multi-step process that requires submitting an inquiry in one system and uploading supporting data to another. *Id.* at 17–18. The AHA told HRSA that it should anticipate the same deficient performance from the same drug companies and third-party vendor.

22. **Permanent losses.** The AHA explained that many of these costs are not recoverable. Paying wholesale acquisition cost rather than the 340B price will result in forfeiture of valuable COGS, prompt-pay discounts, and sub-ceiling pricing that our members have access to today. *See* AHA Letter at 25.

23. **Non-economic harms.** The AHA's comment letter explained the many non-economic harms HRSA's rebate program would cause. The AHA wrote:

Even if every rebate is paid on time and in full, that is, at a minimum, \$200 or \$500 million [in administrative costs] each year that cannot be spent on patient care. As a matter of basic logic, HRSA has to understand that these new administrative and related costs will have non-economic impacts by diverting resources away from caring for "more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12 (1992).

Id. at 29. Our letter further explained some of the specific types of patient harms that would result from a rebate program, often citing to comment letters submitted by covered entities: “It will jeopardize essential service lines—including oncology, labor and delivery, behavioral health, opioid treatment, and more. It will undermine patient assistance programs that subsidize 340B drugs for vulnerable patients. And in some cases, it will directly restrict access to needed medications.” *Id.* at 32.

24. **Benefits.** The AHA explained that HRSA overstates the size of the duplicate-discount problem it claims the rebate program will solve. AHA Letter at 42 & n.47. The AHA explained that HRSA’s own audit data demonstrate that duplicate discounts have declined sharply since 2018. Specifically, the AHA incorporated a prior comment letter from the 2025 Rebate Program’s administrative process that explained:

HRSA’s own 340B audit data show that between fiscal years (FY) 2018 and 2022, audit findings across 340B hospitals for duplicate discount and diversion decreased by a combined 62%. Only 10.7% of 340B hospital audits had at least one finding of diversion; just 13.2% had a duplicate discount finding in FY 2022. As with any program as regulatorily and operationally complex as 340B, hospitals have adapted their 340B programs to better maintain compliance with all rules and regulations.¹⁶

I also am aware that several AHA members reported that HRSA’s audits of their own facilities found no duplicate discounts at all.

25. **The rebate mechanism provides no remedy.** The AHA also explained that the 340B statute bars drug companies from denying discounts until they have completed the statutory audit and dispute resolution processes. AHA Letter at 43–44. It further noted HRSA has taken this position since 1994, when the agency issued a Final Notice stating: “A manufacturer

¹⁶ Am. Hosp. Ass’n, Comment Letter on Application Process for the 340B Rebate Model Pilot Program at 9 (HRSA-2025-14998) (Aug. 27, 2025), <https://www.aha.org/system/files/media/file/2025/08/aha-comments-to-hrsa-on-proposed-340b-rebate-model-pilot-program-letter-8-27-2025.pdf>.

may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions." *Id.* at 44. On top of that, our letter explained that, since 1996, HRSA has taken the position that "[m]anufacturers must continue to sell at the statutory price during the audit process.... Not until the entity is found guilty of prohibited activity and a decision is made to remove the entity from the covered entity list, will the manufacturers no longer be required to extend the discount." *Id.* (quoting Manufacturer Audit Guidelines and Dispute Resolution Processes, 61 Fed. Reg. 65,406, 65,408 (Dec. 12, 1996)). Consequently, the AHA explained, "if drug companies must provide 340B discounts regardless of suspected program integrity concerns, it is unclear how a rebate model can advance any purported program integrity goals." *Id.* at 46.

26. **Reliance.** HRSA's RFI asked whether covered entities' "reliance interests are reasonable in light of the Secretary's express statutory authority to provide for discounts via 'rebate or discount[.]'"¹⁷ The AHA explained that this incorrectly framed our members' reliance interests. AHA Letter at 38–39. We explained that AHA members built their pharmacy operations, their financial planning, and their patient programs around (1) a mechanism HRSA used consistently for thirty-three years; (2) HRSA's own pronouncements in 1994 and 1998 applying the appropriate legal standard when approving a rebate mechanism for one type of covered entity; and (3) HRSA's repeated public statements and court filings defending upfront discounts as recently as August 2025. In *American Hospital Association v. Kennedy*, Defendants "agree[d]" that those interests were "significant," 164 F.4th at 34, and the AHA explained why it

¹⁷ 91 Fed. Reg. at 7,289.

was wrong to abandon that conclusion simply because the agency had discretion to adopt a different payment mechanism.¹⁸

27. **Less costly alternatives.** The AHA urged HRSA to adopt a less burdensome alternative—in particular, a single neutral third-party clearinghouse for claims data, building on the 340B claims repository for Medicare Part D that the Centers for Medicare & Medicaid Services was then developing, has implemented as of October 1, and has proposed to make mandatory for 2028. AHA Letter at 46–49. I am aware that numerous other commenters recommended the same alternative. The AHA also reminded HRSA that Defendants have told two federal courts of appeals that drug companies “have other options available to them” and “alternate means to deduplicate discounts.” *Id.* at 40.

28. **The dispute resolution process.** The AHA explained that HRSA must create a dedicated process for resolving disputes between covered entities and manufacturers, *id.* at 51–52, and described what that process must contain to reduce costs and burdens on covered entities: a designated human point of contact to receive complaints and follow-ups, a clear, specified procedure for addressing them, and a fixed deadline—no longer than thirty days—for resolution.

29. **Additional comment period.** The AHA asked that if HRSA proceeded with a rebate program, it provide a further comment period on the program’s actual specifics before any manufacturer application was approved. *Id.* at 53.

30. **Financial environment.** The AHA’s comment letter described the severe financial headwinds that hospitals will face in 2027. It explained: “[A]s HRSA evaluates the financial impact of its program, it must do so in the context of the overall financial picture facing hospitals at this time. HRSA must provide a reasoned explanation for imposing the costs of the

¹⁸ *Am. Hosp. Ass’n*, 820 F. Supp. 3d at 43.

Rebate Program *on top of* the costs of the OBBBA and other developments. Even if HRSA anticipates some benefits from conducting a test at some point, *now is not that time*[.]” *Id.* at 38.

Defendants Did Not Meaningfully Respond to the AHA’s Comments

31. I have reviewed the Notice in detail. In it, HRSA states that it “carefully reviewed and evaluated all comments,” “conducted a systematic assessment of stakeholder input,” and “considered both the substance and the evidentiary support of the comments received.”¹⁹ I respectfully disagree. HRSA failed to respond to many of the important problems identified in the AHA’s comment letters, as well as those in the hundreds of comment letters submitted by our members and other covered entities.

32. On my reading, the Notice follows a consistent pattern: it acknowledges in general terms that covered entities submitted detailed cost and burden estimates, but it does not meaningfully engage with that information. In some instances, it entirely ignores comments about other important aspects of the problem. When it does address certain problems, it states without analysis that those estimates “rest on assumptions that do not align with the design of the Pilot.”²⁰ Importantly, the Notice does not provide a second comment period, as the AHA and others requested, to submit comments based on the specific design of the Program. Nor did HRSA give covered entities any opportunity to comment on the manufacturers’ plans before approving them on October 1, 2026. Instead of addressing the problems and data that the AHA and others describe, Defendants wave them away in conclusory fashion while adopting the assertions of drug companies and their technology vendors without scrutiny.

¹⁹ 91 Fed. Reg. at 48,888.

²⁰ *Id.* at 48,893.

33. **The five-hour estimate.** A clear example is the number on which HRSA’s entire cost figure rests. In 2025, HRSA estimated that a ten-drug rebate program would generate two hours per covered entity per week of paperwork burden. In its February 2026 ICR and RFI, HRSA contemplated a program two-and-a-half times larger—twenty-five drugs instead of ten—and estimated that it would take two-and-a-half times as long to comply, *i.e.*, five hours per week per covered entity.²¹ The agency has never disclosed what data supports either figure. HRSA did state at one point that this five-hour number was the “median” amount of time required for data submission. The AHA asked HRSA, in plain and direct terms, to produce a chart of the below-five-hour estimates that would allow HRSA’s estimate to sit at the median. Ex. 1 at 29. HRSA ignored that request and has never published a single piece of data in support of its labor-hour figure.

34. The closest HRSA has come to explaining its labor-hour figure was in its Supporting Statement. In that document, HRSA acknowledged (1) receiving 180 comments on the February request and 263 on the June request; (2) that they “primarily addressed the estimated paperwork burden”; and (3) that “[n]umerous commenters submitted organization-specific burden estimates that substantially exceeded HRSA’s estimate.”²² It nevertheless disposed of all of these “organization-specific burden estimates” in a single paragraph, asserting that “many estimates assumed reporting requirements that will not be included in [the] Pilot[.]”²³ Again, HRSA did not respond to commenters’ request to submit additional comments once HRSA settled on its program design. HRSA also stated, in conclusory fashion, that it “continues to believe that the estimated burden reasonably reflects the average paperwork burden associated

²¹ HRSA has since approved plans covering eighteen drugs but has not changed its cost estimate.

²² Supporting Statement at 6–7.

²³ *Id.* at 7.

with the information collection, across more than 15,000 covered entities, while recognizing that actual burden may vary among respondents.”²⁴ Again, HRSA did not provide any data to support its “belie[f]” regarding the “average” estimated paperwork burden.

35. HRSA’s Supporting Statement changed two things, however. It raised the pharmacist wage from \$132 to \$135.50 an hour, which moved HRSA’s own total cost estimate for data submission from the \$523,345,680 in the Notice to \$537,222,270—roughly \$14 million more. And it changed HRSA’s description of the five-hour figure from a “median” burden to an “average” burden, without explanation or acknowledgment that those are different measures of a distribution.²⁵ As with its prior “median” figure, HRSA did not provide any supporting data for its “average” calculation.

36. **Reconciliation.** Reconciliation is the category of incremental administrative cost that our members identified as the single largest omission from HRSA’s cost estimate. In the Notice, HRSA stated that covered entities “already perform extensive administrative functions under the 340B Program,” including “reconciliation activities.”²⁶ That answer is incorrect. Under the upfront discount mechanism, there is no rebate to reconcile because the discount is applied at the point of purchase. Therefore, it is inaccurate to say that covered entities “already perform ... reconciliation activities.” HRSA also asserted that “established technologies, including automated claims processing, batch data submission, and TPAs, can be leveraged to facilitate rebate submission and reconciliation with minimal manual intervention once implemented.”²⁷ HRSA did not identify which technology products it was referring to, what that technology costs, or why the many covered entities who explained that manual reconciliation would be necessary

²⁴ *Id.*

²⁵ Compare *id.* at 11 (“average burden”), with 91 Fed. Reg. at 35,990 (“median burden”); see also Ex. 1 at 29.

²⁶ 91 Fed. Reg. at 48,892–93.

²⁷ *Id.* at 48,894.

(and costly) were wrong. The Approved Plans, which HRSA did not publish until October 1, 2026, make reconciliation harder still. Instead of a single set of rules, covered entities must comply with ten separate manufacturer plans that do not all treat the same claim the same way. For drugs that also carry a Medicare maximum fair price, for example, some Approved Plans reserve the right to deny the 340B rebate, while others pay the rebate and instead reduce the maximum fair price refund—and manufacturers have reserved the right to change their approach after the Program begins. Covered entities therefore cannot build a single, automated reconciliation process. Instead, they must learn each manufacturer’s rules, track every claim against the governing rules, monitor for ongoing changes, and evaluate each denial under a different standard.

37. **Staffing.** While I have not read every comment letter in the administrative record, I can estimate that hundreds of commenters told HRSA they would have to hire new employees to comply with a rebate mechanism. HRSA responded that “any staffing impacts will generally be modest,” that additional staffing “may be absorbed within existing operational structures or supported through existing third-party arrangements,” and that commenters “provided only estimates of anticipated staffing impacts.”²⁸ On my reading of the Notice, HRSA cited no evidence for the proposition that existing third-party arrangements could absorb this work, and our members—who have on-the-ground knowledge of the implementation burden—told HRSA the opposite in the many comments that I have reviewed.

38. **Startup costs.** HRSA agreed that there would be “legitimate startup activities” and that such costs are “inherent to the adoption of a new operational approach.” But it then

²⁸ *Id.* at 48,891, 48,893.

excluded the entire category of startup costs on the ground that they “will be transitional,” without further evaluation.²⁹

39. **Vendor, administrator, and audit costs.** HRSA assigned no value to increased third-party administrator and vendor fees, information technology support, and financial audits—costs that the AHA documented to range from \$150,000 to more than \$750,000 per hospital annually. HRSA’s response was that covered entities “already perform extensive administrative functions,”³⁰ but it did not measure or further address these costs.

40. **Float.** HRSA did not quantify any of the float evidence in the record. HRSA wrote that it “expects the cash-flow impacts on covered entities to be minimal” because the ten-day rebate deadline “is intended to precede the payment deadlines associated with standard wholesaler payment terms,”³¹ and it “believes that the Pilot is unlikely to result in unstable cash flow for covered entities, as certain commenters have predicted.”³² HRSA did not respond to the AHA’s comments that wholesaler payment terms often require payment in fewer than ten days. Nor did it address the comments regarding other aspects of float costs, including escrow requirements, bond covenants, lost COGS and prompt-pay discounts, and the need to divert limited cash-on-hand away from critical services and payroll requirements.

41. **Delays and denials.** The AHA and other commenters explained why HRSA needed to factor in delays and denials in rebating covered entities. Drawing on experience with the Medicare refund processes that these same manufacturers operate through the same Second Sight Solutions technology, the AHA and covered entities explained that those payments are routinely late, misclassified, or wrongly denied, and that each contested claim takes staff time to

²⁹ *Id.* at 48,893–94.

³⁰ *Id.* at 48,892–93.

³¹ *Id.* at 48,895.

³² *Id.* at 48,894.

fix. HRSA did not dispute any of that, but it never attempted to put a dollar figure on the cost and cash flow consequences of delays and denials.

42. **Benefits and duplicate discounts.** The stated purpose of the Rebate Program is to prevent duplicate discounts. But HRSA never measured how many duplicate discounts exist in the 340B program, nor how many duplicate discounts this rebate mechanism could potentially avoid. The Notice conceded as much, acknowledging that “there is no federal estimate of the financial extent of duplicate discounts in 340B.”³³ On my reading of the Notice, HRSA merely repeated two figures from drug industry comment letters. At the same time, the Notice was silent as to the evidence submitted by the AHA and others that undermines those figures, including HRSA’s own audit data, which show duplicate discounts declining since 2018, and the many hospitals that reported clean audit records over as much as a decade.

43. **Alternatives.** The AHA and other commenters suggested numerous alternatives that would not shift additional costs onto hospitals. HRSA cast them all aside. Its principal reason for rejecting the alternatives was that they “would not inform whether rebates are an efficient means of effectuating the 340B ceiling price ... and therefore would fail to advance the central purpose of the Pilot.”³⁴ On my reading, that is self-justifying, circular logic. HRSA rejected each alternative to a rebate mechanism because it was not a rebate mechanism. The AHA’s comment letter directly criticized “[s]uch circular reasoning,” but HRSA again never responded. AHA Letter at 34.

44. Where HRSA did engage with a specific alternative, its analysis was no better. For example, the AHA and other commenters proposed a neutral clearinghouse for claims data, modeled on a repository the Centers for Medicare & Medicaid Services was building at the time

³³ *Id.* at 48,887.

³⁴ *Id.* at 48,890.

and has now implemented. HRSA rejected this option, stating it is “not explicitly authorized under the 340B statute.”³⁵ The AHA’s comment letter specifically called upon HRSA to explain its legal reasoning, but the Notice did not do so.³⁶ Its other stated reason for denial was that, “unlike a clearinghouse, a rebate model by its very nature incentivizes covered entity compliance as a prerequisite to receiving 340B discounts.”³⁷ On my reading of the Notice, HRSA provided no evidentiary support for this conclusion, and it is materially identical to a sentence in a comment letter submitted by a pharmaceutical trade organization.³⁸ Thus, HRSA answered the commenters who proposed the clearinghouse by adopting, nearly word for word, *a drug industry* trade association’s speculation about *covered entities’* intentions. In addition, the drug companies’ own choices also demonstrate that they—not covered entities—lack the incentive to participate in a Rebate Program. Because participation is voluntary for drug companies, each manufacturer may choose which of its eligible drugs to include in the Rebate Program and which to withhold. Multiple manufacturers chose not to include a particular eligible drug in the Rebate Program (even though one of those manufacturers included a different eligible drug). I understand that these drugs were withheld because the manufacturers feared losing market share to competing products outside the Rebate Program. Defendants never addressed these incentives when rejecting less burdensome alternatives. What’s more, if duplicate discounts imposed the costs that drug companies claim, those manufacturers would have every reason to subject *all* of their eligible drugs to a rebate mechanism. Instead, they concluded that protecting market share

³⁵ *Id.* at 48,900.

³⁶ AHA Letter at 48 (explaining that HHS has not “publicly presented its legal reasoning, and there is serious reason to question it,” and stating that “HRSA must subject its legal analysis to public scrutiny”).

³⁷ 91 Fed. Reg. at 48,900.

³⁸ *Compare id.* (“As manufacturer commenters have observed, unlike a clearinghouse, a rebate model by its very nature incentivizes covered entity compliance as a prerequisite to receiving 340B discounts.”), *with* Pharm. Rsch. & Mfrs. of Am., Comment Letter, HRSA-2026-0001-1895, at 14 (“Unlike a clearinghouse, a rebate model, by its very nature, incentivizes covered entity compliance as a precursor to receiving the 340B discount.”).

for certain drugs mattered more. In my view, those choices confirm that the duplicate-discount problem the Pilot purports to solve is overstated, and that drug companies are using the Rebate Program only where it serves their competitive interests. Their own choices prove why the AHA's proposed alternatives were the better course.

45. **Patients, communities, and timing.** The Notice recites several of the patient harms commenters described but then concludes, without analysis, that HRSA “does not anticipate that the Pilot will materially impair covered entities’ ... ability to furnish services to patients.”³⁹ It acknowledges comments warning that patients may have to “go elsewhere and potentially travel far distances to obtain necessary medications—a problem that is particularly acute for rural communities,”⁴⁰ but then says nothing further about them. Nor does the Notice acknowledge this Court’s finding last year that hundreds of millions of dollars spent on administrative costs is hundreds of millions of dollars that cannot be spent on patient care.

46. **Financial environment.** HRSA does not address the financial environment facing hospitals in 2027. It provided no answer to the many commenters that raised this issue, nor did it explain why it must implement a Rebate Program *at this time*.

47. **Dispute resolution.** Despite the AHA asking HRSA to create a dedicated process for resolving disputes, HRSA has not done so. Instead, HRSA has stated that it will publish a dispute resolution process within thirty days of the Program taking effect.⁴¹ Until that day comes, however, covered entities must challenge rebate denials through the Beacon platform and with the drug companies themselves. For many covered entities—particularly small and rural hospitals—this leaves dispute resolution unavailable as a practical matter. These covered entities

³⁹ 91 Fed. Reg. at 48,899.

⁴⁰ *Id.* at 48,898.

⁴¹ *Id.* at 48,895–96.

do not have the staff, systems, or financial resources to track each denial, assemble the supporting documentation, and pursue challenges with each manufacturer. For them, a denied rebate will often simply go unpaid.

The Rebate Program Is Harming—and Will Continue to Harm—the AHA’s Members and Their Patients

48. Our members have informed the AHA that even temporary outlays of the cash required to purchase drugs at wholesale acquisition cost can have severe consequences. For example, it is common for 340B hospitals to use bond financing for projects that expand patient care, and those bonds typically carry covenants requiring the hospital to maintain a minimum number of days of cash-on-hand. Forced expenditures under this program threaten to push some members below those thresholds. And as the AHA has explained to HRSA, a covenant breach carries consequences that range from a credit rating downgrade to a higher cost of borrowing to closure of the facility.

49. Members also have told the AHA that the uncertainty and liquidity risks this program creates have already changed what they are able to plan for—deferring expansions of patient services, facility improvements, and new service lines that would have expanded access to care. Those harms are happening now, before the program takes effect.

50. Members also have told the AHA that the program jeopardizes the patient programs they fund with 340B savings, including free and discounted medication programs, community health screenings and vaccine clinics, other vital service lines, and free or reduced-cost care for uninsured patients. With so many members operating on very thin or negative margins, they inform the AHA that they have no excess funds to sustain current service levels if they must absorb the many costs associated with the Rebate Program.

51. Some members have informed the AHA that the Rebate Program's compliance costs would approach or exceed their 340B savings, forcing them to withdraw from the 340B Program altogether. That consequence, in the AHA's view, is antithetical to the purpose of the 340B Program. We do not believe that Congress would create a program that is so costly that expected participants could not, in fact, participate.

52. Our members have informed the AHA that they have operated in reliance on the upfront discount mechanism for more than three decades and have built their operations, pharmacy workflows, and compliance practices around it. Our members expect to need at least one, and in many cases more than one, additional full-time employee to comply—employees who must be paid for with funds that otherwise serve the hospital's mission. Submitting claims-level data to drug companies, tracking rebates owed, reconciling paid and denied claims, and challenging denials will require resources that would otherwise go to patient care.

53. The costs imposed under the Rebate Program are not recoverable. Because Plaintiffs bring a challenge under the Administrative Procedure Act, our members cannot recover the money they spend complying with this Program even if it is set aside, and our members have already begun incurring those costs. The AHA and other commenters, including many of our own members, brought each of these harms to Defendants' attention during a process designed to collect exactly this information. Defendants have not addressed them. They have instead approved ten manufacturers' plans and raced ahead toward a January 1, 2027 effective date.

54. The 340B program exists so that safety-net providers can stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. Defendants' rebate program would require those same providers to spend more than a billion dollars a year, thereby forcing them to do the opposite. Likewise, in exercising its

discretion to choose a payment mechanism, the Secretary must select the one that is most effective and most efficient from the standpoint of covered entities. As the administrative record amply demonstrates, a rebate mechanism does not satisfy this legal standard.

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

Executed this 7th day of October, 2026 at Washington, D.C.

/s/Chad Golder
Chad Golder

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION,
THE MAINE HOSPITAL ASSOCIATION,
EASTERN MAINE 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.

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 President of the Maine Hospital Association (“MHA”), 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, my review of MHA’s business records and of publicly reported State data, and information provided to me by 340B personnel at MHA’s member hospitals with direct knowledge of those matters.

2. I joined MHA in 2010 and served as Vice President, Government Affairs and Communications, until I became President of MHA in March 2026. As President, I am responsible for the Association’s operations and for its advocacy at the state and federal levels, and in my prior role I was responsible for all of the Association’s communications. Before joining MHA, I was a government affairs professional for the Maine Municipal Association.

3. I earned my undergraduate degree from the University of Notre Dame and my law degree from Boston College.

4. I am familiar with Defendants' plan to replace the 340B program's current discount model with a rebate program starting on January 1, 2027, for twenty-five popular drugs. On April 16, 2026, MHA submitted a comment letter to Defendant Engels in response to the Health Resources and Services Administration's (HRSA) Request for Information ("RFI") regarding a 340B rebate model, setting out the costs such a program would impose on our member hospitals and urging HRSA to abandon it.¹ HRSA nonetheless announced the program in a notice published on August 3, 2026 (the "Notice"),² and on October 1, 2026 it published the rebate plans it had approved for ten manufacturers covering eighteen drugs (the "Approved Plans").³ I have reviewed the Notice and the relevant plans. I also know the harm that this rebate program will cause MHA's members if it goes into effect.

MHA's Members Are the Safety Net in a Rural State

5. 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. Our mission is to support our members in improving the health of their patients and the communities they serve. Twenty-five of our thirty-two member hospitals currently participate in the 340B program.

6. Our members provide essential, around-the-clock medical care across the State of Maine. Half of them are critical access hospitals—small acute care facilities with limited services and no more than twenty-five inpatient beds.

¹ Letter from Me. Hospital Ass'n to Thomas J. Engels, Adm'r, Health Res. & Servs. Admin. (Apr. 16, 2026), HRSA-2026-0001-1530.

² 91 Fed. Reg. 48,883 (Aug. 3, 2026).

³ The Approved Plans are posted on HRSA's website. See Health Res. & Servs. Admin., *340B Rebate Model Pilot Program*, <https://www.hrsa.gov/opa/340b-model-pilot-program> (last visited Oct. 5, 2026).

7. Maine has been losing hospital capacity for a decade. Four hospitals have closed, and others have shut down individual service lines. The loss of obstetric care has been especially severe. Maine hospitals have closed ten labor and delivery units within the past decade.

8. The Maine Health Data Organization (“MHDO”) is the state agency that maintains Maine’s all-payer claims database and collects hospital financial and 340B data. MHDO’s most recent hospital financial report shows that the median operating margin for Maine hospitals was 0.35 percent and the median number of days of cash on hand was 9.3. A hospital operating on nine days of cash cannot absorb additional demands on its liquidity simply so that HRSA can run an experiment.

The 340B Program Sustains Maine’s Hospitals

9. Twenty-seven Maine hospitals participated in the 340B program during fiscal year 2024—the most recent year for which the State has published data—and those hospitals realized more than \$300 million in total savings.⁴ I understand that the participation rate of Maine hospitals in the 340B program in 2026 is similar to what MHDO reported for 2024.

10. Our members put those savings back into their communities through, among other things, 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, including the provision of naloxone, suboxone, and methadone.

⁴ Me. Health Data Org., *340B Drug Program Transparency Report 3* (2026).

Maine's Hospitals Built Their Operations on the Upfront Discount Model

11. Our member hospitals designed their pharmacy operations, wholesaler arrangements, third-party administrator contracts, and annual budgets around an upfront discount, because that is the only model HRSA has ever used. They build those savings into the budgets that fund service lines, staffing, and charity care. They also budget a year in advance.

12. A shift to a rebate mechanism would not simply delay a payment. It would require our members to fund, out of cash they do not have, the same discount they have been receiving at the point of purchase for three decades. Our members did not build their operations around an upfront discount out of preference. They did so because that is the only way the program has ever worked, and because HRSA gave them no reason to plan for anything else.

Maine's Hospitals Will be Forced to Float the Wholesale Acquisition Cost of These Drugs

13. In preparing this declaration, I solicited information from the 340B professionals in MHA's member systems about what Defendants' rebate program would require of them.

14. Collectively, our members distribute all eighteen drugs included in Defendants' rebate program.

15. Our members' wholesaler payment terms cannot accommodate a rebate. Among our member systems, payment terms vary from seven to fifteen days. Due to the practical realities of claims submission, however, our members will be forced to float the wholesale acquisition cost of the drugs included in Defendants' rebate program, regardless of their wholesaler payment term.

16. Defendants' ten-day rebate payment clock does not begin when a drug is dispensed. It begins when a manufacturer receives a complete claim, and our members report that building a claim takes days to weeks. Claims are pulled and submitted on reporting cycles

rather than one at a time, so a claim is already days old before it can be sent. Overall, our members estimate that the full period from dispense to rebate ranges from roughly eleven days at the fastest, for drugs administered in the hospital, to as long as a month for contract pharmacy prescriptions. And our members describe even those figures as a best-case scenario they are unlikely to achieve in practice. Thus, our members will be forced to float the wholesale acquisition cost of these drugs while awaiting a rebate, notwithstanding a ten-day payment window. Some hospitals have informed me that doing so will result in a high likelihood that a rebate mechanism would put them at risk of violating their bond covenants.

HRSA Has Underestimated the Administrative Burden

17. MHA quantified this burden for HRSA in April. Including the twenty-five drugs HRSA referenced in its RFI, we estimated that Maine's 340B hospitals would incur approximately \$55 million in annual incremental administrative and operational costs, driven by added and diverted staff, information technology systems, third-party vendors, compliance activities, and building a process for challenging denials. We estimate that implementation would require our member hospitals to hire roughly thirty-five additional full-time employees collectively, or else to pull clinical staff off patient care to perform administrative work. We told HRSA that its calculations of these costs were extraordinarily inaccurate and understated, and that its estimate of five hours per week was a gross underestimate. HRSA's Approved Plans for eighteen drugs have not meaningfully changed that assessment. And, if anything, our members' experience with the MFP Program indicates that these estimates remain low. It even appears that HRSA has never attempted to measure the time required for backend reconciliation of claims, including challenging claim denials, but our members anticipate this backend work will be the most time-consuming part of Defendants' entire rebate mechanism.

18. HRSA has also assumed that the data its program requires is already collected in the ordinary course. It is not. During the prior iteration of the Rebate Program, both HRSA and the drug companies insisted that hospitals already provide the required information through 340B ESP. That is incorrect. One of our member systems reports that this data is not currently collected from any platform in the fashion a rebate model requires, and that compliance would mean writing new reports and pulling data from seven separate systems spanning its electronic health records, its third-party administrators, and its contract pharmacy platforms. Another member reports that the required fields are not tracked in a single source output, that extracts would have to be modified and pulled from multiple sites of care, and that those fields are not among the data its third-party administrators request today.

19. Our members also cannot prepare for a dispute process that does not exist. Defendants do not intend to publish an ADR process until approximately thirty days after the program takes effect, but we understand that our members will be required to challenge rebate denials with both Beacon and the drug companies themselves. A process that forces hospitals operating on nine days of cash to pursue denied rebates against drug companies, with no assurance that Defendants will ever take action when payments are late or denied improperly, will be so burdensome that it will be functionally unavailable to our members.

A Less Burdensome Alternative Exists, and Defendants Have Not Explained Why It Will Not Work

20. MHA does not dispute that preventing duplicate discounts between the 340B program and the Medicare Drug Price Negotiation Program is a legitimate—albeit subsidiary and non-statutory—objective. But this rebate mechanism is not the least burdensome way to achieve it. Drug companies have other available options, and we urged HRSA to adopt a neutral third-party clearinghouse instead. At a minimum, we asked HRSA to explain why a clearinghouse is

neither viable nor less costly than a rebate mechanism. It has not done so. Absent any quantification of issues with the upfront discount model, and given the costs I have described, there is no reason to impose a rebate mechanism on Maine's hospitals.

Maine's Hospitals Will Have to Cut Clinical Services and Delay Capital Projects if the Rebate Mechanism Goes Into Effect

21. We also asked our members what they would have to cut if the rebate mechanism took effect. Some hospitals said they would no longer be able to subsidize physician practices or to provide behavioral health, substance use treatment, or labor and delivery services. Many would delay or cancel capital projects already planned—emergency department renovations, electronic medical record installations, and expanded emergency transportation among them.

22. Maine's hospitals are already operating on razor-thin margins and nine days of cash. Defendants' rebate program threatens to put further financial stress on our state's healthcare system, which we cannot absorb without adverse consequences for the communities our members serve.

23. In my comment letter, I explained that "HRSA's desire to test a rebate model is seemingly based on the incorrect premise that it must balance the interests of 340B hospitals and drug companies when choosing a discount mechanism. In reality, HRSA must give primacy to the needs of covered entities"⁵ HRSA never responded to this comment and instead stuck with its balancing approach. In so doing, HRSA chose a payment mechanism that was not the most effective and most efficient from the standpoint of Maine's 340B hospitals. The costs and burdens discussed above conclusively prove that.

⁵ Letter from Me. Hospital Ass'n to Thomas J. Engels, HRSA-2026-0001-1530, at 1.

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

Executed this 6th day of October, 2026 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,
EASTERN MAINE 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.

DECLARATION OF LAURIE KANE-
LEWIS IN SUPPORT OF PLAINTIFFS'
MOTION FOR A TEMPORARY
RESTRAINING ORDER

I, Laurie Kane-Lewis, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am the Chief Executive Officer of DFD Russell Medical Centers (“DFD Russell”), a federally qualified health center serving Central and Western Maine. DFD Russell is a 340B covered entity that would be compelled to leave the 340B Program due to Defendants’ rebate program, if it goes into effect. I submit this declaration, not as a plaintiff, but in support of Plaintiffs’ motion for a temporary restraining order. The facts in this declaration are based on my personal knowledge and experience, my review of DFD Russell’s business records, and information provided to me by DFD Russell personnel with direct knowledge of those matters.

2. I have served as Chief Executive Officer of DFD Russell since 2004. Before that, I was Assistant Director and Chief Financial Officer of the Maine Primary Care Association, beginning in 1996. I have worked in non-profit healthcare my entire career, and I have worked with the 340B program since its inception.

3. I am familiar with Defendants' plan to replace the 340B program's current discount model with a rebate program for twenty-five popular drugs, starting January 1, 2027. I am also familiar with the notice the Health Resources and Services Administration ("HRSA") published on August 3, 2026 (the "Notice"),¹ and its October 1, 2026 approval of ten rebate plans covering eighteen drugs (the "Approved Plans").² I have reviewed the Notice and the relevant Plans and know what a shift from discounts to rebates would mean for DFD Russell: we could not remain in the 340B program at all.

DFD Russell Serves a Rural, Elderly, and Low-Income Population

4. DFD Russell provides primary care, including behavioral health, psychiatric care, medication-assisted therapy for substance use disorders, and preventive dental services to the people of Central and Western Maine from three locations. Behavioral health and psychiatric care are scarce in our area, and for many of our patients we are the only realistic source of that care.

5. Our service area is very rural. Our patient population skews elderly, and approximately 40 percent of our patients are covered by Medicare or are dually eligible for Medicare and Medicaid.

DFD Russell's Financial Condition Has Deteriorated Sharply

6. In 2021 and 2022, DFD Russell's overall net income was \$644,267 and \$512,098, respectively. Since then, we have lost money every year: \$167,840 in 2023, \$55,260 in 2024, and \$159,428 in 2025, and we are projected to lose \$493,063 in 2026. We are surviving on savings.

¹ 91 Fed. Reg. 48,883 (Aug. 3, 2026).

² The Approved Plans are posted on HRSA's website. See Health Res. & Servs. Admin., *340B Rebate Model Pilot Program*, <https://www.hrsa.gov/opa/340b-model-pilot-program> (last visited Oct. 5, 2026).

7. We currently have 40 days of cash on hand. Two years ago, we had more than 90. Our burn rate is roughly 25 days of cash per year.

8. We have already taken drastic measures to stay open. In August 2025, we closed our Bridgton location for lack of funding. We have also terminated a patient assistance coordinator position, eliminated two registered nurse positions, and did not fill our behavioral health position when our licensed clinical social worker retired.

9. We have not given cost-of-living raises in two years, which has made retention difficult.

10. We are also absorbing reimbursement shortfalls. The State of Maine has not provided a cost-of-living increase to our Medicaid prospective payment system (“PPS”) rate in two years, and the Medicare PPS rate does not cover the cost of providing services. In addition, the One Big Beautiful Bill Act takes effect in January 2027—the same month Defendants’ rebate mechanism would take effect—adding further downward pressure on our Medicaid revenue.

The 340B Program Was DFD Russell’s Only Margin, and It Was Already Disappearing

11. The 340B program has never been a windfall for DFD Russell. Together with pandemic relief funds, our 340B savings were the only positive margin we had in 2021 and 2022.

12. We use our 340B savings to fund, among other things, behavioral health services, patient assistance, and nurse care managers. For years, we wrote off behavioral health services that patients’ insurance did not cover, but we stopped doing that this year. We have also cut nurse care manager positions.

13. In recent years, our 340B net revenue has collapsed. In 2022, DFD Russell realized \$1,072,712 in net 340B revenue. In 2023 the net was \$919,241, and in 2024 it was

\$913,800. In 2025, however, it fell to \$230,337. Through July of this year, our net 340B revenue was just \$94,319.

14. The cost of participating in the program has nearly tripled while the benefit has fallen. Our 340B program expenses have risen from \$267,600 in 2022 to an annualized \$727,652 in 2026. In three months of 2026—February, April, and July—the 340B program cost DFD Russell more than it returned. Thus, in those months, participating in a federal drug discount program made this health center poorer.

15. These losses have been driven in large part by large chain pharmacies such as Walmart, Hannaford, and Walgreens no longer paying the 340B differential.

DFD Russell Cannot Float the Wholesale Acquisition Cost of the Rebate Program Drugs

16. DFD Russell prescribes eleven of the eighteen drugs included in Defendants' rebate program.³ A transition to purchasing at wholesale acquisition cost would require DFD Russell to front the full WAC of those drugs and then wait to be repaid through rebates.

17. DFD Russell is operating with a negative cash flow. We have lost money every year since 2023 and are drawing down our remaining cash reserves just to keep our doors open. We cannot front any additional cash to drug companies, much less take on the existential risk of non-payment.

18. My liquidity concerns are only compounded by the fact that there are no objective parameters that would require Defendants to take action against a drug company that fails to timely pay rebates or that inappropriately denies rebates. Instead, Defendants' enforcement

³ Those drugs are: Eliquis, Enbrel, Farxiga, Januvia, Jardiance, Breo Ellipta, Janumet, Linzess, Tradjenta, Trelegy Ellipta, and Vraylar.

mechanism is purely discretionary, and drug companies could face no consequences for missing ten-day payment windows that threaten our survival.

DFD Russell Does Not Have the Staff or the Systems to Comply

19. DFD Russell administers its 340B program with existing staff who already have other responsibilities.

20. HRSA estimates that its rebate program would require five hours of work per covered entity per week and suggests that the work can be absorbed within existing operations.⁴ That estimate clearly undercounts the administrative burden, particularly when you include backend reconciliation of paid and denied claims, which I believe would be the most labor-intensive part of the entire rebate mechanism.

21. Simply put, we have no one to absorb these additional responsibilities. We have already been forced to eliminate a patient assistance coordinator, two registered nurse positions, and a behavioral health clinician, and we have not given a cost-of-living raise in two years.

22. We have no one left to take on this work, and a health system that has cut positions and frozen raises for two years does not have the resources to hire a new, specialized employee for Defendants' rebate mechanism.

DFD Russell Would Be Forced to Exit the 340B Program if Defendants' Rebate Mechanism Goes Into Effect

23. At our current run rate, the 340B program nets DFD Russell approximately \$161,690 a year, down from \$1,072,712 in 2022. The costs to divert staff or hire a new employee to take on the burden of administering the rebate mechanism would exceed the entire remaining benefit of the program.

⁴ 91 Fed. Reg. 35989, 35990 (June 15, 2026).

24. More simply, if Defendants' rebate program takes effect, the costs of participating in the 340B program would exceed its benefits, and DFD Russell would have to leave the program altogether. When that happens, the services our 340B savings support—behavioral health care provided without regard to insurance coverage, patient assistance, and nurse care management—will have to be cut or diminished. Our patients would have to travel for hours to obtain the care we provide them locally today, and for behavioral health and psychiatric care, there is frequently no alternative provider accepting new patients at any distance.

25. In sum, DFD Russell has used the 340B program for decades to reach patients who have nowhere else to go. If Defendants' rebate mechanism takes effect, it will drive out of the program the very kind of provider it was created to support.

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

Executed this 6th day of October, 2026 at Leeds, Maine.

/s/ Laurie Kane-Lewis
Laurie Kane-Lewis

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION,
THE MAINE HOSPITAL ASSOCIATION,
EASTERN MAINE 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.

DECLARATION OF MARK
BERTILRUD IN SUPPORT OF
PLAINTIFFS' MOTION FOR A
TEMPORARY RESTRAINING ORDER

I, Mark Bertilrud, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am the Chief Executive Officer of Unity Medical Center ("Unity") in Grafton, North Dakota. I have been the CEO at Unity since January 2026 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, my review of Unity's business records, and information provided to me by Unity personnel with direct knowledge of those matters.

2. I have worked in healthcare administration for over forty years. I began my career in 1986 with the Lutheran Hospitals & Homes Society in various administrative roles until 1993. At that time, I moved to Michigan and spent several years working with the American Retirement Corporation at their locations in Holland, MI, and East Lansing, MI, as their Executive Director until 2002. I joined the physician office practice of ProCare Systems that year and served as an Executive Director for several of their medical practices until 2009. After four

years in a private business startup, I returned to an Executive Director role at Eventide Senior Living Communities in Moorhead, Minnesota, in 2013 and served in that role until 2016. From 2016 through 2024, I was the Executive Director of Warroad Senior Living Center in Warroad, Minnesota. In 2024, I became the Chief Operating Officer at Unity and assumed the Chief Executive Officer role in January 2026.

3. I earned an undergraduate degree in Business Administration with a concentration in healthcare management from Concordia College in Moorhead, MN.

4. I am familiar with Defendants' plan to replace the 340B program's current discount model with a rebate program starting on January 1, 2027, for twenty-five popular drugs. On April 17, 2026, Unity submitted a comment letter to Defendant Health Resources and Services Administration ("HRSA") in response to its Request for Information regarding a 340B rebate model pilot program.¹ HRSA nonetheless announced the program in a notice published on August 3, 2026 (the "Notice"),² and on October 1, 2026, it published the rebate plans it had approved for ten manufacturers covering eighteen drugs (the "Approved Plans").³ I have reviewed the Notice and the relevant plans. I also know the harm that this rebate program will cause Unity if it goes into effect.

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 over

¹ Letter from Unity Med. Ctr. to Health Res. & Servs. Admin. (Apr. 17, 2026), HRSA-2026-0001-1690.

² 91 Fed. Reg. 48,883 (Aug. 3, 2026).

³ The Approved Plans are posted on HRSA's website. *See* Health Res. & Servs. Admin., *340B Rebate Model Pilot Program*, <https://www.hrsa.gov/opa/340b-model-pilot-program> (last visited Oct. 5, 2026).

10,000 patients. We operate a fourteen-bed Critical Access Hospital and two primary care Rural Health 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 HRSA as a medically underserved area.⁴ U.S. Census Bureau data shows that the median income in Grafton is approximately twenty percent below the median income in the state of North Dakota, and just under seventeen percent of Grafton residents hold a bachelor's degree or higher.⁵ Grafton's employment participation rate is approximately sixty percent, and eighteen percent of our citizens have a disability.⁶ The primary industries in the area are agriculture and manufacturing.

7. Unity Medical Center offers a range of critical service lines, including inpatient and swing-bed care, emergency services, oncology, infusion services, surgery, cardiac and pulmonary rehabilitation, chronic disease treatment, mental health counseling, radiology, laboratory, respiratory care, maternity care, foot care, nutritional counseling, and diabetes management. We have primary care clinic locations including walk-in same-day access and physical, occupational, and speech therapy in Grafton and in Park River, ND. Additionally, we provide telemedicine programs and specialty provider access through our clinic space. We have won numerous awards and recognition for our care, quality, and culture, including recognition as a top 100 Critical Access Hospital. Unity also provides education for students at all levels of interest in health careers from middle school through college, including medical students

⁴ Health Res. & Servs. Admin., *MUA Find*, <https://data.hrsa.gov/topics/health-workforce/shortage-areas/mua-find> (last visited Oct. 5, 2026).

⁵ U.S. Census Bureau, *Grafton, ND*, https://data.census.gov/profile/Grafton_city,_North_Dakota?g=160XX00US3831820 (last visited Oct. 5, 2026).

⁶ *Id.*

interested in serving a rural population in conjunction with the University of North Dakota's 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 addressed in some way by purchasing vans to transport patients when other options are not available to them to access their healthcare needs.

9. 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.

The 340B Program Built the Services Unity Provides Today

10. Unity has participated in the 340B program since 2016. And in 2026 our facility saved \$1.6 million through the program's discounted pricing model. Unity's operating margin is less than three percent at \$2.2 million, and we have a limited amount of cash on hand. Our annual 340B savings accounted for approximately seventy-three percent of Unity's 2026 net margin. An earlier declaration unintentionally understated the 2025 impact, which was approximately \$716,000 rather than \$550,000, and the significant increase since that time has been driven by the addition of retail pharmacy outlets to the program.

11. The 340B program is the heartbeat of our operations, and our 340B savings are incorporated into our overall operating budget, which has allowed us to expand service lines, improve our facilities, and administer a financial assistance program for eligible patients. The facilities, skilled teams, and services we offer would not be possible without the substantial impact of 340B savings.

12. For example, we have recently added and expanded cardiac and pulmonary rehabilitation services and hired employees to staff each of them. In addition, we have started

chronic care management and health coaching to support our patients in monitoring and seeking care to best manage their ongoing health concerns. In 2021, we opened a thirty-six-thousand-square-foot, three-story addition to modernize our 68-year-old hospital. The savings from the 340B program were incorporated into the financial feasibility study we submitted in applying for loans through the USDA and the Bank of North Dakota; those savings were an integral part of the financial ratios that allowed us to be approved for the financing. We are still servicing approximately \$19.6 million of principal balance on these outstanding loans. As part of the new addition, we built surgical suites, hired and contracted with surgeons, and acquired surgical equipment we otherwise could not have afforded. We are anticipating the opening of a new primary clinic in our Park River location in November of 2026. Once again, the funds created through our 340B savings have been a significant part of our confidence in making these investments in our delivery system.

13. We also built an enhanced hospital-based pharmacy and have now hired pharmaceutical staff, including the addition of a second registered pharmacist. We renovated our thirty-six-year-old clinic using 340B savings, and we have purchased two vans to improve patient access to care. Losing any of these services would leave a significant healthcare void in our community.

14. We have planned additional projects that depend on 340B savings as well. Our current inpatient pharmacy, part of the original 1958 hospital, is in serious need of modernization and expansion. We have been planning that expansion for years and have held fundraising activities through our UMC foundation over the past couple of years. We have entered the design phase of that project, and we are currently working on final space layout and pricing. We have submitted requests for related equipment funding through the Rural Health Transformation

Program as well. If Defendants' rebate program takes effect, it would likely remove this project from our anticipated capital improvements moving forward, and modernization of the space would not be possible. Cash flow impacts and additional expenditures related to the program would give us significant pause in moving forward. In addition, all system-wide anticipated expenditures for capital would need to be heavily scrutinized and reduced or eliminated as cash flows and profit margins would make such investments increasingly difficult or impossible to fund.

Unity Cannot Float the Wholesale Acquisition Cost of the Rebate Program Drugs

15. Unity administers fifteen of the twenty-five drugs HRSA included in its Request for Information and ten of the eighteen drugs in the Approved Plans.⁷ Our current outlay for all twenty-five drugs is a little over \$500,000 annually. A transition to purchasing at average wholesale price acquisition costs would require Unity to front an additional \$274,000. A critical access hospital of our size with restricted liquidity cannot provide effectively interest-free financing to manufacturers while awaiting rebates. That capital investment opportunity is diverted from frontline patient care and our mission of keeping care local.

16. Because Defendants' ability to take action against drug companies when they fail to timely pay rebates or inappropriately deny them is purely discretionary, I have great concern that the rebate program will put our liquidity at risk. Drug companies could face no penalty for missing their payment timing obligations or improperly denying or delaying a rebate. Without specific and mandatory enforcement parameters, I both fear and expect they will not pay on time or will refuse to pay at all. The anticipated rebate model, even if functioning well, would be filled with added cost, delays in payment, and almost assuredly a reduction in the total dollars

⁷ Those drugs are: Eliquis, Farxiga, Januvia, Breo Ellipta, Janumet, Linzess, Tradjenta, Trelegy Ellipta, Vraylar, and Xtandi.

returned to the organization. An inefficient system, and the resulting administrative burden in tracking, submitting, monitoring, and resolving claims is overwhelming to consider.

The Dispute Process Is Functionally Unavailable to Unity

17. Defendants do not intend to publish an actual dispute resolution process until approximately thirty days after the rebate program goes into effect, but Defendants' public statements indicate that covered entities will be required to challenge rebate denials with Beacon and the drug companies themselves. The administrative dispute resolution process will therefore be functionally inaccessible to a facility of Unity's size and resources.

18. Filing a complete claim requires a forensic level of data reconciliation. For each disputed national drug code ("NDC"), Unity must provide evidence of the 340B ceiling price, the actual price paid, and proof of patient eligibility. Preparing a single ADR petition could take specialized staff up to 40 to 60 hours. At our internal labor rates, the cost of preparing a claim would often exceed the value of the rebate being claimed. Our ability to withstand payment delays and/or pay for the cost of recovery actions will be prohibitively significant in staff and legal costs.

19. In addition, the ten-day rebate repayment window resets every time a manufacturer identifies an issue with a claim. Manufacturers are thus incentivized to cycle through repeated ten-day requests for information, exhausting our administrative resources before the dispute process even begins. Waiting indeterminate periods of time for rebates that might never be paid—while fronting a huge portion of our available cash to drug companies—could and will likely lead to a liquidity crisis for Unity.

20. The disparity of resources between drug companies and covered entities like ours allows manufacturers to use technical denials as an attrition strategy, knowing a critical access hospital cannot afford to contest them.

Unity Does Not Have the Staff or the Systems to Comply

21. Unity designed its technological systems and operational infrastructure in reliance on an upfront discount model. We simply do not have the staff needed to comply with a rebate program. At a facility of our size, each staff member necessarily wears multiple hats; very few roles are dedicated to a single job. Unity estimates a requirement of the equivalent of one to two specialized full-time employees to manage the burden of complying with the rebate program, including submitting claims and reconciling payments and denials. These hours would accumulate from staff throughout our operations to identify, track, and gather data, prepare submissions, track progress, and ultimately resolve disputes and discrepancies. Staff from clerical, technical, and professional levels would need to be involved.

22. Should we need to employ additional expertise, 340B-trained professionals command total compensation packages upward of \$160,000. For Unity, that expense could consume a large part of the entire benefit of the program. These professionals are also not in great supply, particularly in rural regions, and I would expect a search to be difficult and lengthy. Taking into account the time required to recruit, hire, and train such personnel, and the additional time required to prepare our data systems, I do not believe Unity could practically be prepared to implement Defendants' rebate program by January 1, 2027.

23. Administering the rebate program would involve two distinct tasks, neither of which can be automated in the way Defendants assume. The first is data submission. The data fields required for our contract pharmacy claims are already collected in the ordinary course of

business, but they reside in different third-party administrator systems. The fields required for medical claims are not as readily available, and assembling them from our electronic health record and our billing systems is substantially more complicated and will require manual compilation.

24. The second task, reconciliation, I expect to be even more costly and burdensome. Because the 340B program has always operated through an upfront discount, Unity has never had to reconcile incoming rebates. Unlike an upfront discount, a rebate would require Unity to match payments received weeks or months later to individual drug purchases and claims; identify claims for which rebates are missing, delayed, denied, or underpaid; investigate discrepancies between our records and manufacturers' determinations; correct or resubmit claims where appropriate; and pursue unresolved amounts with manufacturers or their vendors. Once a payment arrives, we cannot simply treat it as undifferentiated revenue. We must determine which underlying 340B transactions the payment covers, match those transactions to our own purchasing and claims records, and then allocate the payment to the appropriate internal accounts, departments, pharmacies, and cost centers. These are not mere bookkeeping formalities. At a facility of our size, this work would fall on the same small group of pharmacy, finance, billing, and information-technology staff who already wear multiple hats, and in many cases, it would require manual investigation that no technology available to Unity can perform for us.

25. The Approved Plans make that reconciliation work harder still, because the same claim will be treated differently depending on which drug it applies to. Claims for drugs that also carry a Medicare maximum fair price ("MFP") illustrate the problem. The Notice permits a manufacturer to deny a rebate for duplication with the MFP only if it provides "rationale and

specific documentation” for the denial.⁸ The Approved Plans do not follow one approach. Some manufacturers reserve the right to reject a 340B rebate claim when the drug is also subject to the MFP. Others will pay the 340B rebate in full and instead reduce the maximum fair price refund paid to the dispensing pharmacy or provider through the Medicare Transaction Facilitator. For the same kind of claim, then, Unity could receive a rebate from one manufacturer and a denial from another, and the drug companies have reserved the leeway to change approach after the program begins. Our staff would have to know each manufacturer’s rules, monitor for changes, and reconcile every denial against a different standard across multiple reimbursement schemes. For a facility where no one is dedicated to 340B full time, that is not realistic.

26. Claims submitted after the 45-day deadline add yet another layer of work. A claim submitted more than 45 days after dispense will be denied, and the Notice only contemplates exceptions for “extenuating circumstances.”⁹ For every claim Unity submits beyond the 45-day window, we will be forced to manually describe the extenuating circumstances and submit a request for consideration “on a case-by-case basis.” But it is unclear what circumstances qualify, how long a request will take, or whether the 45-day clock pauses while a request is pending. Given the data-collection problems described above, Unity expects that some claims will inevitably miss the window through no fault of our own.

The Rebate Program Threatens to Turn Unity’s 340B Benefit into a Liability

27. Taken together, Defendants’ rebate program would impose on Unity upwards of \$200,000 in additional annual labor costs and, based on Unity’s experience, an estimated

⁸ 91 Fed. Reg. at 48,903.

⁹ *Id.* at 48, 902.

\$125,000 each year in rebates denied on technical grounds and never recovered. Those recurring costs alone consume roughly one quarter of the benefit of our 340B program.

28. But the more fundamental concern is liquidity. The program would require Unity to advance up to approximately \$2.5 million in wholesale acquisition costs each year and await repayment from manufacturers. That number would almost certainly grow over time as the initial program is expanded to additional drugs in the future. Unity simply does not have the unrestricted cash available to lend to manufacturers, particularly when there is no guarantee of either timely repayment or repayment at all.

29. If the previous numbers are even remotely accurate, Unity will no longer be able to use and distribute our 340B savings as we have. Our service lines will be reduced, and our community will be forced to seek more distant options for care currently delivered here, or those services may simply be unavailable.

30. 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. It would transform a vital safety-net program into a profit-retention tool for manufacturers.

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

Executed this 6th day of October, 2026 at Grafton, North Dakota.

/s/Mark Bertilrud
Mark Bertilrud

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION,
THE MAINE HOSPITAL ASSOCIATION,
EASTERN MAINE 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.

DECLARATION OF MATTHEW J.
MARSTON IN SUPPORT OF
PLAINTIFFS' MOTION FOR A
TEMPORARY RESTRAINING ORDER

I, Matthew J. Marston, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am the Vice President, Clinical Ancillary Services, and Chief Pharmacy Officer of Eastern Maine Healthcare Systems, dba Northern Light Health, the integrated health delivery system of which Plaintiff Eastern Maine Medical Center ("EMMC") is a member hospital. In that role, I am responsible for pharmacy operations across the Northern Light system, including administration of the 340B drug pricing program at each of Northern Light's covered entities.

2. I am familiar with Defendants' "340B Rebate Model Pilot Program" ("Rebate Program") and with the significant operational and financial harms that the Rebate Program will cause EMMC if implemented.

3. On April 17, 2026, Northern Light Health submitted a comment letter to Defendant Engels in response to HRSA's Request for Information regarding a revised Rebate Program. The letter explained why a rebate mechanism would impose substantial costs, burdens, and harms on our system that far outweigh any benefits that may come from such a fundamental switch. HRSA

nonetheless proceeded with its Rebate Program, announcing in an August 3, 2026 notice (the “Notice”) that the Program would begin on January 1, 2027. On October 1, 2026, HRSA announced that it approved applications to participate in its Rebate Program from ten drug companies, covering eighteen drugs (the “Approved Plans”). Across Northern Light Health’s eight 340B covered entities, we dispense all eighteen drugs in the Approved Plans (and all 25 drugs that HRSA referenced in the Notice).

4. 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, my review of EMMC’s and Northern Light Health’s business records, and information provided to me by EMMC and Northern Light Health personnel with direct knowledge of those matters.

Professional Background

5. I have worked in hospital pharmacy and health system administration since 2012. I began at EMMC as a pharmacy practice resident in 2012, served as a clinical pharmacist on its inpatient oncology unit from 2013 to 2015, and served as its Clinical Oncology Specialist from 2015 to 2017, where I led compliance with United States Pharmacopeia Chapter 800 for the Eastern Maine Healthcare System and represented oncology on the hospital and health system pharmacy and therapeutics committees. From 2017 to 2018 I was Senior Manager of Clinical Pharmacy Services at Miller Drug, the system’s retail pharmacy. I joined Northern Light Pharmacy in 2018 as Interim Director of Pharmacy, became Director of Pharmacy in 2019 and Associate Vice President in 2020. In 2021, I joined Northern Light Health as Vice President and Chief Pharmacy Officer. Since September 2025, I have served as Vice President, Clinical Ancillary Services and Chief Pharmacy Officer of Northern Light Health, with responsibility for laboratory,

imaging, medical transport, and pharmacy services across Northern Light Health, including the 340B program at each of its covered entities.

6. I earned my Doctor of Pharmacy from the Massachusetts College of Pharmacy and Health Sciences and my Master of Business Administration, with a focus on healthcare administration, from Husson University. I have been a Fellow of the American College of Healthcare Executives since 2024.

Background on EMMC

7. EMMC is a 411-bed tertiary medical center in Bangor, Maine, which is in Penobscot County. EMMC provides inpatient and outpatient infusion services, a broad range of specialty services, primary care,¹ a Level II trauma center,² a neonatal intensive care unit,³ and pediatric services.

8. EMMC is the primary referral hospital for northern and eastern Maine. It cares for some of northern and eastern Maine's most underserved populations, including patients with complex chronic conditions and significant social and economic challenges. For many of our patients, especially those living in rural communities, EMMC is the closest facility where they can receive care.

9. EMMC is designated as a disproportionate share hospital because it treats a significant number of low-income patients. Approximately 18 percent of the Bangor population

¹ EMMC provides three-quarters of the primary-care services in the Bangor area.

² EMMC is an American College of Surgeons-verified Level II Trauma Center. Its trauma program works with more than 20 referring hospitals across a service area roughly the size of New Hampshire, Vermont, and Massachusetts combined, and approximately half of the seriously injured patients admitted to EMMC are transferred from community-hospital emergency departments. EMMC is also a base for LifeFlight of Maine, which provides critical-care air transportation for seriously ill and injured patients.

³ As the only Level III Neonatal Intensive Care Unit (NICU) north of Portland, Eastern Maine Medical Center cares for more than 450 newborns each year, including about 150 who begin their fight for life in other hospitals.

lives below the federal poverty level and nearly 21 percent receive disability benefits.⁴ Medicare or Medicaid pay for approximately 49 percent of EMMC's patient care. Defendant Health Resources and Services Administration has designated Penobscot County as containing medically underserved areas.⁵

10. In 2026, EMMC received CMS's five-star overall quality rating—the highest rating CMS awards—and was the only Maine hospital to receive it. Only about 10% of hospitals nationwide receive five stars.

EMMC's Ongoing Financial Challenges

11. Between 2019 and 2025, Northern Light Health as a whole lost \$ 324 million from operations. EMMC's net losses accounted for 20 percent of that total. EMMC's operating margin in 2024 was negative 7.1percent.

12. Those financial challenges continue today. Through June of this year, Northern Light Health's operating loss for the fiscal year was \$37,000,000.

13. In response to these ongoing financial challenges, EMMC has been forced to reduce its services and cut staff. In December 2022, we downsized our acute rehabilitation inpatient unit. We closed our audiology clinic in August 2024 after losing our providers to a private practice that opened in the area. We closed our pain clinic in June 2025 when the last remaining providers left to open a private practice of their own. We closed our walk-in clinic in September 2025 because we could not recruit and retain providers. And since September 2025, EMMC has reduced its workforce by 125.3 full-time equivalents.

⁴ U.S. Census Bureau, *Bangor, ME*, https://data.census.gov/profile/Bangor_city,_Maine (September 25, 2026).

⁵ Health Res. & Servs. Admin., *MUA Find*, <https://data.hrsa.gov/topics/health-workforce/shortage-areas/mua-find> (September 25, 2026).

14. EMMC anticipates further financial pressure in 2027 and is budgeting accordingly. Beginning in January 2027, the One Big Beautiful Bill Act (“OBBA”) is expected to cause many patients to lose coverage under MaineCare, Maine’s Medicaid program. Based on a Kaiser Family Foundation analysis of that lost coverage, EMMC has budgeted a \$6.1 million increase in bad debt and free care for fiscal year 2027. Importantly, the Rebate Program is scheduled to take effect at precisely the same time that OBBA—and its resultant effects on bad debt and charity care—will take effect.

EMMC’s Participation in the 340B Program

15. EMMC has participated in the 340B Program since October 1, 2003. Year-to-date through June, EMMC’s 340B savings for 2026 are \$79,000,000.

16. EMMC uses 340B savings to support its non-profit mission. For example, we use 340B savings to subsidize service lines that do not cover their own costs but remain vital to the communities we serve. EMMC also uses those savings to underwrite free and discounted medications for patients. We use 340B savings to support the charity care and community health programs EMMC provides to patients who cannot pay. EMMC relies on 340B savings to help fund the equipment and facility investments that keep these services available. And our 340B savings also help pay the nurses, physicians, pharmacists, and other staff who deliver this care. The costs imposed by the Rebate Program will directly impair our ability to fund these important services, projects, and positions.

17. During the entire time it has participated in the 340B Program, EMMC has always operated under an upfront-discount payment mechanism. It has designed its hiring, operations, third-party contractual relationships, information technology systems, and financial planning in reliance on an upfront-discount mechanism. A shift to a rebate mechanism would require EMMC

to revamp these features, requiring a substantial new investment of resources far above and beyond what we have budgeted for.

The Rebate Program Will Impose Massive Administrative Costs on EMMC

18. To even get up and running so we can participate in the Rebate Program, EMMC will incur substantial one-time costs to build infrastructure that does not exist today. Our initial estimate of the information technology effort for report development and integration alone is 140 hours, at an estimated cost of \$150 per hour. There will be additional startup costs, including legal and compliance review; staff training; development of new policies, procedures, and compliance controls; changes to our accounting and Enterprise Resource Planning systems; and more.

19. The costs will increase once the Rebate Program is live on January 1, 2027. HRSA estimates that the Program will require only five hours of work per covered entity per week; it states that additional staffing will be unnecessary because the burden can be absorbed within existing operational structures or through existing third-party arrangements. Based on my firsthand experience, this is not accurate for EMMC.

20. Northern Light Health operates a centralized 340B program staffed by a program director and seven to eight analysts. To comply with Defendants' Rebate Program, we would need at least two additional analysts—pharmacy technicians or entry-level finance positions—at a recurring cost of approximately \$123,000 per year in total compensation. Critically, however, experienced 340B professionals command total compensation well above that figure and are not in great supply, particularly in a rural state, meaning the cost for this labor could be even higher—especially as all of the covered entities in Maine are pursuing the same limited pool of labor. In addition, hiring a pharmacy technician takes us an average of fifty-two days from posting to start date, and a candidate with the pharmacy or compliance experience this work requires would take

considerably longer to find. New 340B staff also must complete Apexus 340B University, and in practice, it takes six months or more before a new analyst can work independently with a high degree of effectiveness.

21. I estimate the Rebate Program also will require approximately eighty additional hours each week just to oversee or correct what our third-party administrator (“TPA”) reports. As such, HRSA is incorrect in the Notice when it states that existing TPA relationships “can be leveraged” without additional cost or burden. To make matters worse, EMMC has numerous 340B sites that do not feed their drug accumulations into the TPA, so those accumulations will have to be *manually* pulled and manipulated for submission. In similar contexts, TPAs frequently make mistakes when reporting this kind of data; therefore, I anticipate that I or others at EMMC will need to manually comb through claims to produce a file for submission for Defendants’ Rebate Program. EMMC staff also will be forced to track the claims throughout the process to ensure the rebate came to our accounts payable, returned to the appropriate internal unit, dig into reasons why claims were denied, and then challenge each denial with the rebate platform or the manufacturer.

22. In addition, our vendors are raising their prices to accommodate the change to the rebate mechanism. Omnicell 340B, our TPA, has quoted an additional \$1,000 per month, and that quote covers *only the submission of pharmacy claim data*. Omnicell does not collect claims data from our 340B sites, which include our infusion centers and many of our provider-based primary and specialty practices, and it cannot extract medical claims data from our electronic health records. Because Northern Light Health uses at least four different electronic health record systems, no vendor and no existing interface can assemble that data for us. Our own staff would have to locate each claim in the record, confirm patient eligibility, reformat the data to the manufacturer’s specification, and submit it manually—on every submission cycle. This is an

entirely new manual process that would have to be designed and implemented. Assembling a compliant submission would require our TPA, outside compliance vendor, and our own personnel to coordinate *on every cycle*. For some required fields, such as Health Plan ID, we have not been able to determine where the data resides or even what the field refers to, because the definitions supplied by the platform vendor and the manufacturers are unclear.

23. Submitting the claim is only the beginning. Rebate reconciliation—which includes tracking the rebates that are paid and denied and challenging denials—will be the most burdensome work of all. We would have to analyze whether a rebate was actually received for each claim, involve our finance team to monitor bank accounts for sums matching those rebates, and build a tracking system that does not exist today. We are investigating additional software that is projected to cost an additional \$200,000 to \$500,000 per year in unbudgeted expense. None of this work is currently required under the upfront-discount mechanism. The Notice is incorrect to state that covered entities “already perform ... reconciliation activities.”

24. Claims submitted after the Rebate Program’s 45-day deadline add yet another layer of work. Under the rules of the Program, any claim submitted more than 45 days after dispense will be denied. Given all of the new work required to submit claims data, this will be a difficult deadline to meet, meaning that EMMC may entirely lose 340B discounts it otherwise would have been entitled to. The only exception to this new 45-day deadline is for what the Notice calls “extenuating circumstances.” But if EMMC were to seek such an exception, EMMC would be forced to manually describe the undefined “extenuating circumstances” and submit the requested exception for consideration “on a case-by-case basis.” It is unclear what circumstances qualify, how long an exception request will take, or whether the 45-day clock pauses while a request is pending. That is additional work that has never existed before in the 340B Program.

25. Taking into account the time required to hire and train new analysts, build these processes, and stand up a reconciliation program, I do not believe EMMC can be prepared to implement Defendants' Rebate Program by January 1, 2027.

**The Rebate Program Will Impose a Range of Expensive
"Float" Costs on EMMC**

26. Across Northern Light Health's eight covered entities, we estimate that the annual increased upfront drug spend under the Rebate Program for all twenty-five drugs would exceed \$20 million; EMMC's share of that outlay is approximately \$14 million. For the eighteen drugs currently approved, Northern Light Health's increased outlay would be \$16 million, and EMMC's would be \$12 million. Thus, of all the many costs that the Rebate Program will impose on EMMC, my most pressing concern is liquidity. EMMC does not have that cash available to lend to drug companies.

Commented [MM1]: Amy Gamble

27. Defendants believe that a 10-day rebate requirement will solve for this liquidity problem. I respectfully disagree. EMMC purchases drugs from our wholesaler on net fifteen-day payment terms. Because Defendants' ten-day rebate clock does not begin until a drug company receives a complete claim, that would leave us less than five days to assemble and submit the necessary claims data if we were to be reimbursed before our wholesaler invoice came due. Given the work required to assemble and submit that data—including, as noted, considerable manual labor—I am not confident EMMC can meet that schedule.

28. Because we will be forced to float the WAC of drugs to manufacturers, EMMC also may need to draw on a line of credit to pay our wholesaler in a timely manner, which will incur interest cost. I am not aware that Defendants have accounted for these interest costs in their cost-benefit analysis.

29. We also estimate that Defendants' Rebate Program will reduce our systemwide days of cash on hand by more than one day and reduce our debt service coverage ratio by approximately half a percent, putting us at risk of violating our bond covenant. I do not believe that Defendants have taken seriously this risk when conducting their cost-benefit analysis. Similarly, the Rebate Program would be damaging to EMMC's earnings and could result in a further downgrade to our ratings. Additional downgrading could cause us to lose access to capital for critical equipment replacements, such as imaging equipment, endoscopy equipment, cardiac catheter lab equipment, and network and server updates. It also would hinder our ability to repair equipment and delay payment to our vendor partners, ultimately forcing EMMC to make difficult choices about which services will remain available to our communities.

30. HRSA's analysis of "float costs" wrongly assumes accurate approvals of our claims and timely rebate payments. Based on my experience with drug companies and my understanding of how their third-party vendor operates, it is unrealistic to assume that drug companies will accurately rebate every claim—and pay every rebate on time. By my own conservative calculations, if manufacturers denied even 15 percent of EMMC's rebate claims, we would lose approximately \$2.1 million each year.⁶

31. The Rebate Program also would cost us more than \$250,000 per year in lost cost-of-goods-sold discounts. These are commonplace discounts that we will never be able to recover.

⁶ Disputing claims would add additional costs. As an initial matter, Defendants do not intend to publish a full dispute resolution process until approximately thirty days after the rebate program takes effect, but we understand that covered entities will be required to challenge rebate denials with Beacon and the drug companies themselves. Filing a complete claim with these entities requires a forensic level of data reconciliation. For each disputed national drug code, we would have to produce evidence of the 340B ceiling price, the actual price paid, and proof of patient eligibility. We estimate that preparing a single administrative dispute resolution petition would take specialized staff approximately 10 hours. This incentivizes manufacturers to cycle through repeated requests for information and exhaust our administrative resources before any dispute process begins. And because Defendants' ability to take action against drug companies (and their chosen platform) when they fail to pay timely or inappropriately deny rebates is purely discretionary, drug companies could face no penalty for slow-walking this process.

This means that EMMC's price tag for the Rebate Program starts at \$250,000 and increases with all the other administrative, "float," and other costs discussed herein.

32. Having worked in the 340B space for much of my career, I am aware that the purpose of the 340B Program is to allow providers like EMMC to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." The Rebate Program does the opposite. By imposing all of the costs and burdens discussed herein, EMMC will reach fewer patients and provide less comprehensive services to patients and communities in northern and eastern Maine.

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

Executed this 8th day of October, 2026 at Brewer, Maine.

/s/Matthew Marston
Matthew J. Marston

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION,
THE MAINE HOSPITAL ASSOCIATION,
EASTERN MAINE 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.

DECLARATION OF ROBERT
NAHOOPII IN SUPPORT OF
PLAINTIFFS' MOTION FOR A
TEMPORARY RESTRAINING ORDER

I, Robert Nahoopii, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am the Senior Vice President of Pharmacy Services at SpendMend LLC ("SpendMend"), a company that, among other things, provides independent 340B compliance audits, program advisory services, and operational support to 340B covered entities. I currently lead SpendMend's pharmacy division. 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, my review of SpendMend's business records, and information provided to me by SpendMend personnel and clients with direct knowledge of those matters.

2. I have worked in hospital pharmacy and 340B program administration since 1999. I began my career at Intermountain Healthcare in Utah and held pharmacy management positions across that system, including pharmacy manager at Intermountain's corporate office, pharmacy operations coordinator at Intermountain Medical Center, pharmacy operations manager at Utah Valley Regional Medical Center, and, from 2010 to 2013, Director of Pharmacy for Utah Valley

Regional Medical Center and Intermountain's Urban South Region. In those roles I was directly responsible for Intermountain's largest 340B DSH hospital and regional support for a smaller DSH hospital, a non-340B hospital, and four critical access hospitals. In 2012, I co-founded Turnkey Pharmacy Solutions, which began by supporting critical access hospitals' ("CAHs") 340B programs and grew into a national 340B consulting and compliance firm. I served as Turnkey's Chief Executive Officer until SpendMend acquired it in August 2020, and I have led the pharmacy practice since the acquisition.

3. I earned my Doctor of Pharmacy from the University of Utah in 2006 and a Master of Science in Pharmacy Administration from the University of Utah in 2008. I completed two years of postgraduate residency training with Intermountain Healthcare, a first-year residency in hospital pharmacy and a second-year residency in hospital pharmacy administration. I am an Apexus Certified Expert in the 340B program ("340B ACE"), 2017. I served on the board of the Utah Society of Health-System Pharmacists from 2008 to 2010.

4. SpendMend serves more than 800 covered entities, spanning virtually every covered entity type recognized under the 340B statute, including disproportionate share hospitals, critical access hospitals, sole community hospitals, rural referral centers, children's and free-standing cancer hospitals, federally qualified health centers, and other federal grantees. Our clients are located in all fifty states. Apexus, the 340B Prime Vendor, has selected SpendMend five times as a Consultant Contributor to help educate the covered entity community.

5. Our work puts us inside the day-to-day operations of our clients' 340B programs. SpendMend has supported more than 200 HRSA 340B audits of its clients and has performed more than 4,000 mock audits over the past 13 years. In that work, we review purchasing records,

dispensing and administration records, patient eligibility determinations, contract pharmacy arrangements, third-party administrator (“TPA”) configurations, and Medicaid billing practices. We also assist clients with manufacturers’ claims-data submission requirements and with the refund process under the Medicare Drug Price Negotiation Program (“MDPNP”).

6. On April 20, 2026, I submitted a comment letter on SpendMend’s behalf to Defendant Engels in response to HRSA’s Request for Information regarding a 340B rebate mechanism.¹ That letter explained, based on SpendMend’s experience across hundreds of covered entities, why any rebate mechanism would impose costs and administrative burdens far greater than HRSA assumed, and it urged HRSA to retain the upfront discount structure that has governed the 340B program for more than thirty years. I adopt and incorporate that letter into this declaration. HRSA nonetheless announced the program in a notice published on August 3, 2026 (the “Notice”),² and on October 1, 2026, it published the rebate plans it had approved for ten manufacturers covering eighteen drugs (the “Approved Plans”).³ I have reviewed the Notice, the Approved Plans, HRSA’s published guidance on the program, and the published materials of Second Sight Solutions, LLC (“Second Sight”), the operator of the Beacon platform that every Approved Plan uses.

Covered Entities Run Their 340B Programs in Many Different Ways, but Every One of Them Is Built Around an Upfront Discount

7. Across the covered entities SpendMend has served, there is great variability in how 340B programs are operationalized. Some entities maintain physical 340B inventory. Most hospitals use a virtual inventory with replenishment. Under that system, drugs are dispensed

¹ HRSA-2026-0001-2074.

² 91 Fed. Reg. 48,883 (Aug. 3, 2026).

³ The Approved Plans are posted on HRSA’s website. See Health Res. & Servs. Admin., *340B Rebate Model Pilot Program*, <https://www.hrsa.gov/opa/340b-model-pilot-program> (last visited Oct. 5, 2026).

from neutral stock, each dispense is evaluated by software to determine whether the patient qualifies, and once eligible dispenses reach a full package, the entity purchases a replacement quantity at the 340B price. Some entities qualify claims with TPA software; other, smaller systems track eligibility *manually, by hand*. Some participate in manufacturers' data-sharing programs through Second Sight's 340B ESP platform; others have declined.

8. Every one of those programs is built around receiving the 340B price at the time of purchase. Wholesaler account structures, split-billing and accumulator software, TPA contracts, contract pharmacy agreements, charity care and patient assistance policies, and annual budgets all assume the discount is received upfront. HRSA's statement that a rebate mechanism would have only a "minimal impact" on covered entities is, in my view, incorrect.

HRSA's Burden Estimate Does Not Resemble Real-World Implementation

9. HRSA estimates that claims submission will take a covered entity roughly five hours per week.⁴ The Notice states that "any staffing impacts will generally be modest," that "in many cases, additional staffing will be unnecessary because they may be absorbed within existing operational structures or supported through existing third-party arrangements," and that only "[i]n limited cases, where operational structures are less sophisticated or TPAs are not utilized," will covered entities need more staff.⁵ None of that matches my own experience working with our clients.

10. After HRSA approved the first rebate pilot in the fall of 2025, SpendMend developed an implementation playbook for its clients. At that time, we estimated most clients needed a minimum of six weeks to prepare, which would require coordination across legal,

⁴ 91 Fed. Reg. 35,989, 35,990 (June 15, 2026); 91 Fed. Reg. at 48,893 & n.20.

⁵ 91 Fed. Reg. at 48,893.

accounting and finance, pharmacy, information technology, and analytics. The legal work included assessment of the non-negotiable terms and conditions imposed by the rebate platform vendor. The information technology and analytics work included assessing, developing, and quality-testing the reports needed to assemble accurate claim-level submissions. The pharmacy and finance work included designing data-submission and reconciliation workflows that do not exist under the upfront discount mechanism, so that the entity could confirm it had actually been paid.

11. Nothing in this year's rebate program reduces that estimate. In fact, the drug list is approximately twice as large as last year's and covers even more manufacturers, so the complexity of preparation has only increased. All told, a covered entity can easily exceed 200 hours of project time simply to begin participating, depending on the complexity of its existing program and how readily its data can be reported. Those startup costs will be incurred before the recurring monthly work begins. Covered entities have already begun adding resources or requesting support from various 340B vendors, and nearly all of this additional support comes at an increased cost and burden to the 340B covered entities. This additional support can be \$15,000 plus per covered entity on the low end.

12. In SpendMend's experience, many covered entities, particularly the smaller 340B programs, cannot complete the work necessary to implement the program on January 1, 2027, and even if the program never goes into effect, all money that covered entities spent preparing is unrecoverable.

Defendants' Rebate Program Will Create New and Burdensome Administrative Work

13. Submitting claims is itself a burdensome new work stream, in large part because the data the rebate mechanism requires is rarely contained in a single system. Contract pharmacy

claims are in each pharmacy's TPA, and large pharmacy chains often require covered entities to use the chain's own administrator or process, each of which has its own portal and file format. In-house pharmacy claims are in the covered entity's own TPA or pharmacy system. Medical claims for drugs administered in clinics and infusion centers are in the electronic health record and billing system, and in SpendMend's experience, most TPAs are either not receiving certain 340B administered drug data or not receiving all the required data elements. A covered entity that uses more than one of these systems must pull data separately from each one for every reporting cycle. Assembling the required fields can therefore mean building connections across disparate systems and compiling claims data by hand.

14. To illustrate this burden, consider the numbers at a moderately sized covered entity with in-house retail pharmacies. The eighteen approved drugs comprise over 300 NDCs. A federally qualified health center with five clinics and five retail pharmacies has ten dispensing locations (*i.e.*, five retail environments and five administered drug environments) and would download roughly 40 reports per month if it decided to upload data weekly. It would then need to aggregate, analyze, and upload the data. This will likely take 30 minutes per report on average and result in 20 hours per month for just the upload portion. Then factor in time and resources needed to review denials and returned reports for missing data for each environment, and then the need to rerun or review data to respond to denials and missing data requests. Finally, a process is needed to reconcile all the output back to the original claims to ensure that rebates were paid appropriately and financial systems reconciled. On a similar note, a health system with ten covered entities, each with a mixed-use pharmacy, an in-house pharmacy, and ten contract pharmacies, would download roughly 48 reports per month per hospital or 480 reports total for

the health system, about 24 hours, or 0.6 of a full-time employee for just data submission per hospital or 6 FTEs for the health system.

15. Mixed-use hospital outpatient data is captured at the dose level, so even a small 340B program generates a significant volume of claims each month, and a large one generates hundreds of thousands of claims.

16. That only accounts for claims submission. Each claim must then be reconciled on the backend, which I estimate will be the most time-consuming aspect of the rebate program.

17. The Notice states that covered entities “already perform ... reconciliation activities” and that technology can support rebate reconciliation “with minimal manual intervention.” 91 Fed. Reg. at 48,892–94. Nothing in my experience supports that assumption.

18. Under a rebate mechanism, staff will have to track each submitted claim individually to determine whether a rebate was paid, whether the amount is correct, whether it was denied and on what ground, and whether it was reduced by a later credit. For each claim, staff will also have to look up which manufacturer’s plan applies, because they set different rules for when the ten-day clock starts and what counts as a valid reason to deny a claim. Beacon reports this information one NDC and one dispensing location at a time, so the work cannot be done in bulk. Staff must collate the data by prescription number and fill number and confirm that the covered entity was made whole. I have also reviewed HRSA’s FAQ, which states that “[c]overed entities should have access to the real-time rebate status of a claim, so they can easily reconcile claims submitted with rebates paid.”⁶ This is insufficient because it appears to be in reference to a single claim versus the ability to review all claims in aggregate against initial submissions and reconcile them with potential Medicare Part D MFP/MTF rebates.

⁶ Health Res. & Servs. Admin., *340B Rebate Model Pilot Program*, <https://www.hrsa.gov/opa/340b-model-pilot-program> (last visited Oct. 5, 2026).

19. The MDPNP adds a second layer. Every approved drug for the rebate program is also a selected drug under the MDPNP, so for each Part D dispense, the manufacturer owes either a 340B rebate or a refund of the difference between the price paid and the Maximum Fair Price (“MFP”). The Approved Plans take varying approaches to that potential overlap. Some Plans reserve the right to reject the 340B rebate. Others pay the rebate and reduce the MFP refund through the Medicare Transaction Facilitator. Therefore, a covered entity that dispenses through its own pharmacy will receive the 340B rebate through Beacon and the MFP refund through the Medicare Transaction Facilitator. Because the two payments come through two separate systems, they arrive on different schedules, and either one might be denied or reduced by a subsequent credit. To confirm that it received the 340B price on a given dispense, then, the covered entity must trace both payments, and any later adjustments, back to that one claim. This is additional reconciliation complexity that was not anticipated during the comment period or in the Notice, which assumed no variation across drug companies.

20. Denied and delayed rebates add a third layer of cost and complexity, because each one must be disputed individually. HRSA’s website directs covered entities to “[f]irst contact the manufacturer and IT platform vendor,” then, after “good-faith efforts,” to email HRSA using a form that calls for several data elements per claim, including the unit wholesale acquisition cost (“WAC”) price, the unit 340B price, the rebate amount, the rejection date, and the rejection reason.⁷ A covered entity dispensing all eighteen drugs will have ten dispute channels to learn and track.

21. SpendMend’s experience with similar systems shows what covered entities can expect those disputes to cost. The data needed to contest a denial—the dispense record, the

⁷ *Id.*

purchase record, the 340B ceiling price on the date of dispense, and the manufacturer's stated reason—are often in different systems. Assembling that data by hand takes up to 10–20 minutes per claim before evaluating whether the denial was appropriate, and there will be additional time required to submit the disputes. Under the approved Rebate Program, this process must play out while the 45-day submission window keeps running, because Beacon's rules do not reset the window when a claim is rejected. A covered entity with 20 denials in a month would likely spend an additional 3–7 hours disputing them. In SpendMend's experience, covered entities often do not have that time, and when the cost of a dispute exceeds the value of the rebate, they stop disputing. I saw this with the MFP rebates this year, where many covered entities simply lost rebates due to the resource burden of challenging the 340B status of a non-340B claim.

22. To deal with the added administrative burden of a rebate mechanism, covered entities have told us that they will be forced to either hire up to two additional employees or engage an outside vendor. I understand that vendors are quoting approximately \$60,000 to \$100,000 per year for their services, even for the smallest covered entities. Many of our clients cannot afford that expense, and even those that can would still need their own staff to review and quality-check the vendor's work. SpendMend itself has been approached by clients to handle their claims submission and reconciliation work; to the extent we can offer this service at all, we will do so at little or no profit because our clients need the assistance and cannot bear the additional expense. We cannot, however, offer those services for free, thus adding costs for the covered entities themselves.

Second Sight's Existing Platform Shows the Added Costs that Covered Entities Should Expect

23. SpendMend has extensive, direct experience working on behalf of covered entities with two systems that resemble the rebate mechanism. The first is the Medicare

Transaction Facilitator, which processes MFP refunds. The second is the 340B ESP platform, which manufacturers use to administer their contract pharmacy restrictions. Drug companies participating in these programs rely on platforms produced by Second Sight, the same vendor that operates the Beacon platform approved for the Rebate Program.

24. SpendMend has been hired by covered entities to perform MFP reconciliation for them. In SpendMend's experience, we have seen error rates approaching forty percent in the system's identification of 340B claims. Compounding that issue, as noted above, the data required to dispute these errors is not readily available on the platform, so each dispute can take up to 15 minutes of staff time to analyze and assemble by hand. I believe the rebate program will require the same work on a larger scale, across more drugs, more manufacturers, and a second payment stream.

25. Claims submission through 340B ESP is similarly rife with inefficiency and error. The rules enforced in the vendor's software add conditions that HRSA has never adopted, and the result is a persistent gap between the claims a covered entity's TPA qualifies and the claims the manufacturer's software will accept. Reconciling that gap takes multiple hours per month per covered entity, and often the result is that the entity simply does not receive 340B pricing on a dispense to a 340B-eligible patient.

26. I believe these errors are the product of added complexity. Every condition a manufacturer adds to 340B pricing is another rule that must be encoded in a price file, transmitted to a wholesaler, and applied correctly to thousands of accounts, and each step is another place for the process to fail. SpendMend has already seen this with contract pharmacy restrictions. A client recently lost 340B pricing on multiple wholesaler accounts for five days because of errors in the price files the wholesaler received from the manufacturer. Defendants'

rebate mechanism multiplies the complexity. Manufacturers must now load WAC pricing into every covered entity's 340B account for the eighteen rebate drugs while leaving 340B pricing in place for all other 340B drugs. I expect that more rules, applied to more accounts, will produce more errors. Under a rebate mechanism, each error costs the covered entity the difference between WAC and the 340B price of a drug until it is manually located, disputed, and resolved.

The Rebate Program Will Deny 340B Pricing on Eligible Dispenses by Design

27. Independent of errors and denials, the design of the Rebate Program guarantees that some dispenses to 340B-eligible patients will never receive the 340B price. I describe three examples drawn from SpendMend's experience.

28. **The transition to the rebate mechanism.** Under the upfront discount mechanism, a covered entity dispenses prescriptions from its regular inventory and, once 340B-eligible dispenses add up to a full package, the entity buys a replacement package at the 340B price. On January 1, 2027, every covered entity will have eligible dispenses that have not yet added up to a full package and so have not been replenished. When the entity buys the replacement after that date, it will pay WAC, and it cannot claim a rebate on dispenses that occurred before the program began. HRSA recognized this problem and therefore allowed rebates on up to two unreplenished packages per drug dispensed in the fifteen days before January 1, 2027. 91 Fed. Reg. at 48,902. In SpendMend's experience, however, unreplenished balances for high-volume drugs such as Eliquis and Jardiance routinely exceed two packages at a single site. The entity will pay WAC for those additional packages with no rebate.

29. **Package purchases.** The Notice requires that rebates be "paid at the unit level," but drugs are purchased by the package. A critical access hospital that must order a non-formulary medication to meet a single patient's need will pay WAC for the entire package, but it

might only dispense one dose from the package and receive a rebate on that one dose. The hospital may never dispense the drug again, and it will wait months or years for the remaining product to expire before it can return it to a reverse distributor for a partial refund. The rebate on that single dose will rarely offset the WAC premium paid for the package. For example, if a bottle of 100 Januvia were purchased on WAC, and only 30 tablets were dispensed as 340B, the covered entity would only receive 30% of its WAC-to-340B savings back while it waited for the additional 70 tablets to be filled. This is a larger issue for closed-door 340B pharmacies only servicing 340B-qualified patients because they may end up carrying the cost on WAC for months, thereby further deteriorating their cash flow and exacerbating financial concerns.

30. **The 45-day deadline.** The Notice requires claims to be submitted within 45 days of dispense. In the ordinary course of operations, that window will routinely be missed through no fault of the covered entity. For example, when a patient receives a drug in the emergency department or an operating room and is then admitted to the hospital as an inpatient, the hospital does not bill for that drug until after the patient is discharged. In my experience, that process could take longer than 45 days. Drugs administered in some infusion centers present a second problem. Covered entities receive administration charge data for those drugs only every 30 days (*e.g.*, the infusion center opens up an encounter at the beginning of the month and closes it at the end of the month for billing multiple visits), and that data does not include every field the rebate mechanism requires. Staff must gather the missing fields by hand, which leaves them roughly two weeks to compile and submit each month's claims before the deadline passes. The practical reality is that some claims will be submitted late. While the Approved Plans allow manufacturers to grant exceptions case by case, a covered entity would have to prepare a written justification

for each late claim, and it often does not have the staff to do that. Therefore, the strict 45-day deadline—for every dispense type—will lead to 340B discounts that are lost entirely.

The Problem the Rebate Program Targets Is Small, and Less Burdensome Alternatives Exist

31. In the Notice, HRSA provides that “there is no federal estimate of the financial extent of duplicate discounts in 340B.” 91 Fed. Reg. at 48,887. SpendMend’s audit experience bears on that question directly. Of the more than 200 HRSA audits of covered entities that SpendMend has supported, very few have resulted in a duplicate discount finding. Of the more than 4,000 mock audits we have performed, duplicate discount risk was not a significant issue as many covered entities focus on ensuring that they are billing appropriately. Thus, even where a duplicate discount finding occurs, the claims at issue represent a small fraction of the 340B claims the covered entity processes. In my experience, moreover, covered entities’ compliance has also improved substantially over the past decade.

32. To the extent there is even a duplicate discount problem worth addressing, less burdensome alternatives exist and are in use today. SpendMend has clients in all fifty states, and in my experience, Oregon’s approach is the most efficient and effective means of preventing Medicaid duplicate discounts. Oregon’s Medicaid program prevents duplicate discounts by collecting covered entity claims data retrospectively and excluding 340B claims from its rebate requests to manufacturers. One reason it works is because the data is shared with a neutral party affiliated with neither covered entities nor manufacturers. A similar process at the federal level, often called “a third-party clearinghouse approach,” would address nonduplication without putting the financial burden on covered entities. In fact, CMS is proposing a similar model for the IRA inflation penalty component of Medicare Part D claims. It is concerning that CMS has

already implemented a clearinghouse data model approach for one part of the IRA and HRSA is using a rebate model for the MFP part.

The Rebate Program Will Divert Resources from Patient Care

33. The harm from Defendants' rebate mechanism will fall hardest on the covered entities with the fewest resources. Federally qualified health centers, in particular, do not have the resources for this program. SpendMend's smaller clients need the most help managing the differences among the manufacturer plans. Many small covered entities track eligibility manually—on paper—because the cost of TPA software would exceed the 340B savings their programs generate. Those entities will have to digitize their records to meet the data submission requirements, submit them within 45 days of each dispense, and perform manual uploads on a recurring basis, all with staff who perform several other jobs. Any delay costs them the WAC premium they have already paid. The alternative, implementing a TPA, diverts those same dollars from patient care. In my experience, the smallest covered entities will bear the largest burden.

34. It also will fall on patients. Many covered entities use 340B pricing to provide prescriptions to patients at no charge. Today, those entities are guaranteed 340B pricing on those prescriptions, subject to their own compliance. Under a rebate mechanism there is no such guarantee. A data error, a technical delay, a missed 45-day window, or an aberrant-quantity rejection means the entity has both given the drug away and paid the highest possible price for it. That is why SpendMend's playbook advised clients to revisit their charity care policies. I expect some safety-net providers to narrow or end those programs rather than accept the risk.

35. Every covered entity that SpendMend serves will be affected. The magnitude will vary, but all will imminently face new administrative burdens, new cash demands, and new ways

to lose 340B pricing on eligible dispenses. Those burdens divert resources from patient care. The costs of preparing for January 1, 2027, are being incurred now, and they will not be recovered if the program is later set aside. Based on more than twenty years in hospital pharmacy and 340B administration, on SpendMend's work with more than 800 covered entities, and conversations with SpendMend's clients, I believe the covered entity community and the providers and patients the program exists to serve will be immediately and substantially harmed by Defendants' Rebate Program.

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

Executed this 6th day of October, 2026 at Draper, Utah.

/s/ Robert Nahoopii
Robert Nahoopii

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION,
THE MAINE HOSPITAL ASSOCIATION,
EASTERN MAINE 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.

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. I am responsible for the strategic and operational direction of NLH's hospital, ambulatory clinics, and nursing home, and for the financial well-being of the institution. 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, my review of NLH's business records, and information provided to me by NLH personnel with direct knowledge of those matters.

2. I began my career in healthcare as a physical therapist. After eleven years as a clinician, I moved to the administrative side and served in leadership roles at hospitals in New York, Illinois, and Pennsylvania. Immediately before joining NLH, I served for eight years as Chief Executive Officer of Community Memorial Hospital in Hamilton, New York.

3. I have spent the majority of my career working in rural healthcare and was formerly 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, 2027, for twenty-five popular drugs. On April 17, 2026, I submitted a comment letter to Defendant Engels on NLH's behalf in response to HRSA's Request for Information regarding a 340B rebate model, explaining why any rebate mechanism would impose costs on NLH far outweighing any benefit.¹ HRSA nonetheless announced the program in a notice published on August 3, 2026 (the "Notice"),² and on October 1, 2026, it published the rebate plans it had approved for ten manufacturers covering eighteen drugs (the "Approved Plans").³ I have reviewed the Notice and the relevant plans. I also know the harm that this rebate program will cause NLH if it goes into 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. The next hospital is two hours away.

¹ Letter from Nathan Littauer Hosp. to Thomas J. Engels, Adm'r, Health Res. & Servs. Admin. (Apr. 17, 2026), HRSA-2026-0001-1623.

² 91 Fed. Reg. 48,883 (Aug. 3, 2026).

³ The Approved Plans are posted on HRSA's website. *See* Health Res. & Servs. Admin., *340B Rebate Model Pilot Program*, <https://www.hrsa.gov/opa/340b-model-pilot-program> (last visited Oct. 5, 2026).

7. Our 74-bed acute care hospital provides emergency services, general surgery, general inpatient services, and specialty services including cardiology, neurology, gastroenterology, obstetrics and gynecology, pediatrics, orthopedics, ophthalmology, and urology. Our 84-bed nursing home provides around-the-clock skilled nursing care to short- and long-term residents, along with medical care, specialty care, and physical, occupational, and speech therapy.

8. 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. Two of them (in Gloversville and Speculator) additionally serve as urgent care clinics with walk-in availability.

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

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

11. Approximately sixty-nine percent of all NLH patient care that is paid for has historically been paid for by Medicare or Medicaid. NLH is designated as a disproportionate share hospital because it treats a significant number of low-income patients, and as a Medicare Dependent Hospital given the high number of Medicare patients in our service area.

NLH Does Not Have the Financial Margin to Absorb New Costs

12. NLH has incurred double-digit negative margins for more than five years, resulting in a decrease of fifty-eight percent to its days of cash on hand. We presently have approximately 110 days of cash on hand and expect a margin of negative ten percent this year.

13. That decline in cash resources has already impaired our ability to meet primary operating costs and to pay necessary vendors on time. Our accounts payable have grown by approximately ninety percent over the past four years. Delayed payments have in some cases increased our interest costs and caused us to forgo early-payment discounts, compounding the underlying problem.

14. A rebate mechanism, which converts an upfront saving into a delayed and uncertain repayment, would make each of these problems worse.

NLH Cannot Float the Wholesale Acquisition Cost of the Rebate Program Drugs

15. NLH has participated in the 340B program since 2012 and currently saves approximately \$1.4 million per year through the program.

16. 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 mechanism will force us to slow or stop the expansion of access to care in the Fulton and Hamilton County communities and restrict our ability to update our facilities and equipment.

17. 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.

18. NLH administers seventeen of the twenty-five drugs referenced in Defendants' rebate program and nine of the eighteen drugs covered by the Approved Plans.⁴ Our current outlay for all twenty-five drugs is approximately \$320,400 annually, and our 340B savings attributable to them are approximately \$694,300. If NLH had to buy all seventeen at wholesale acquisition cost, it would have to front up to approximately \$1,014,700 in 2027.⁵

19. A rebate mechanism would force NLH to provide drug companies an interest-free loan while we await discounts we are owed by statute. Given the state of our cash resources, I project that the change would have significant cash flow impacts that would leave NLH further unable to meet financial obligations across many areas of its operations. That burden could put at risk the organization's ability to obtain credit, to continue operating without significant cuts to services, and to serve this community.

NLH's Experience with the Medicare Transaction Facilitator Shows the Ten-Day Promise Is Illusory

20. The Notice provides that the rebate payment period is ten days. NLH already participates in a rebate program that provides a meaningful benchmark for what that promise is worth. Under the current payment process for Medicare Transaction Facilitator claims, it has been our experience that claims are paid in approximately thirty to ninety days, depending on the manufacturer and the drug, even though the payment period is supposed to be fourteen days. That payment delay has already proven burdensome to our organization. I have no reason to

⁴ Those drugs: Trelegy Ellipta, Januvia, Breo Ellipta, Farxiga, Linzess, Jardiance, Otezla, Enbrel, and Eliquis.

⁵ It is not possible for NLH to calculate the prospective 2027 purchase data for only the nine drugs covered by the Approved Plans.

believe the drug companies would perform materially better under Defendants' rebate program, and there are no mandatory consequences if they do not.

21. Because Defendants' decision whether to take any action against drug companies that pay rebates late or inappropriately deny them is entirely discretionary, I have great concern that the rebate program would put our liquidity further at risk. Given that NLH is a small hospital, I expect we would be unevenly matched against drug companies in any dispute and would have little practical recourse.

NLH Does Not Have the Staff or the Systems to Comply

22. NLH cannot provide exact figures for the increased cost of a rebate model. But based on preliminary discussions with our third-party administrator and our third-party compliance vendor, I anticipate significant start-up and maintenance charges. We estimate, for example, \$45,000 in additional costs annually for only our third-party administrator and third-party compliance vendor. On top of that, we estimate third-party consultation fees at \$18,000 annually.

23. NLH's pharmacy staff currently coordinates our participation in the 340B program. That staff does not have the capacity to administer a rebate program on top of its existing work, and I anticipate increases in labor far in excess of HRSA's estimate of five hours per week. We estimate that we would need to add at a minimum one additional full-time employee ("FTE") to cover internal compliance, data submission, reconciliation, audit support, and, where applicable, challenges to denials. The cost of this FTE would be approximately \$55,000 annually including salary and benefits.

24. For the fourteen years NLH has participated in the 340B program, we have built our pharmacy operations, our third-party administrator and compliance vendor arrangements,

and our financial planning around the upfront discount model that has governed the program since its inception. The data this rebate mechanism requires is not data our systems easily produce today. NLH engages a third-party compliance vendor to assist with the collection, submission, retention, validation, and maintenance of our manufacturer restriction compliance activities; that vendor must access each third-party administrator's system to download, validate, and submit the data. To supply the data the rebate model would require, our third-party administrator, our compliance vendor, and NLH personnel would all have to coordinate to ensure accurate submissions. It is unlikely that our third-party administrator would be able to extract the required medical claims data from our electronic health record at all, which would require an entirely new manual process to be designed and implemented. These changes would impose a burden far in excess of what HRSA has estimated.

25. And that does not even include the labor hours required for backend reconciliation, which I expect to be the most burdensome part of the entire rebate mechanism. This work stream, which does not exist under the upfront discount model, would require new staff or draw on staff from across our organization to identify and track rebate claims, gather supporting data, follow up on late or unpaid rebates, and dispute denials.

26. The Approved Plans would make that reconciliation work even more difficult, because the drug companies have not agreed to treat the same kind of claim the same way. The clearest example involves drugs that also carry a Medicare maximum fair price ("MFP"). The Notice allows a manufacturer to deny a 340B rebate as duplicative of the MFP only if it supplies "rationale and specific documentation" for the denial.⁶ But the ten manufacturers whose plans HRSA approved have taken different positions on how they will handle those claims. Some have

⁶ 91 Fed. Reg. at 48,903.

reserved the right to deny the 340B rebate outright when the drug is also subject to an MFP. Others have said they will pay the 340B rebate and instead reduce the MFP refund to the pharmacy or provider through the Medicare Transaction Facilitator. As a result, NLH could submit two essentially identical claims and have one paid and the other denied, depending only on which company made the drug, and each company has kept the ability to change its approach once the program is underway. For a pharmacy staff as small as ours, learning ten different sets of rules, monitoring for changes to each of them, and reconciling every denial against a different standard and across multiple reimbursement schemes is not a marginal addition to the workload. It is a new job entirely.

27. The Notice's 45-day submission deadline adds still more work. Under the Notice, a claim submitted more than 45 days after the drug is dispensed will be denied unless NLH can show "extenuating circumstances."⁷ Claims with extenuating circumstances will then be evaluated "on a case-by-case basis." Given the manual data extraction I describe above, I expect that some of our claims will miss that window. Each time that happens, a member of our staff will have to write up the circumstances, submit a request for an exception, and then follow up on it. Nothing in the Notice tells us what circumstances will qualify, how long a decision will take, or whether the clock stops while a request is pending. We would be asking for exceptions without even knowing the standard.

28. Taking into account the time required to recruit, hire, and train new personnel, to design a manual data extraction process that does not exist today, to coordinate that process across two outside vendors, and to implement a backend reconciliation workflow that also does

⁷ *Id.* at 48,902.

not exist today, I do not believe NLH can be prepared to implement Defendants' rebate program by January 1, 2027.

The Rebate Program Has Already Changed What NLH Can Plan For

29. The prospect of this program has forced NLH to make major adjustments to its strategic plan. Where we had been planning five years out, we have scaled back to two years.

30. We have also paused projects that would expand access to care. Although we have received donated property for a new primary care clinic and have donors lined up, we have not been able to move forward with it. Our retail pharmacy build-out also remains on hold. We first paused these projects last year in response to Defendants' rebate program, but within weeks of that program being set aside, Defendants signaled that a larger one was coming. So, the projects remain on hold.

31. If the rebate program takes effect, we would also have to scale back investments in necessary medical equipment and could be forced to forgo critical services for this community. We have even written into our third-party administrator contract renewal the option to reconsider whether NLH will remain in the 340B program at all if a rebate program does not make us financially whole. We have never had to do that before.

Defendants Have Identified No Problem at NLH That a Rebate Program Would Solve

32. To date, no manufacturer has approached NLH regarding a 340B or Medicare Drug Price Negotiation Program duplicate discount issue. Manufacturer-initiated audits of 340B covered entities are already extremely rare, with the most recent data available indicating that HRSA received only two final audit reports from manufacturers between November 2022 and September 2024. In my view, the existing administrative dispute resolution process therefore

sufficiently addresses any manufacturer concerns about duplicate discounts without imposing a rebate model on hospitals like ours.

33. NLH is the only hospital in a poor, rural, and aging community, and the 340B program is a substantial part of what allows us to remain one. Defendants' rebate program would take resources we use for patient care and spend them recovering discounts we are already owed.

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

Executed this 8th day of October, 2026 at Galway, Ireland.

/s/Sean Fadale

Sean M. Fadale

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION,
THE MAINE HOSPITAL ASSOCIATION,
EASTERN MAINE 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.

DECLARATION OF TRAPPER
DENTON IN SUPPORT OF
PLAINTIFFS' MOTION FOR A
TEMPORARY RESTRAINING ORDER

I, Trapper Denton, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am the Chief Executive Officer of Dallas County Medical Center ("DCMC") in Fordyce, Arkansas. I have served as Chief Executive Officer since May 2026 and am responsible for DCMC's 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, my review of DCMC's business records, and information provided to me by DCMC personnel and consultants with direct knowledge of those matters, including matters predating my tenure as Chief Executive Officer.

2. I have worked in healthcare since 2009. I began my career as a physical therapist assistant with Lifepoint Health, where I worked from October 2009 to May 2016, and then served as Rehab Director from May 2016 to December 2022. I joined DCMC in December 2022 as Financial Controller, became Chief Financial Officer in April 2025, and was appointed Chief Executive Officer in May 2026.

3. I earned a Bachelor of Applied Science from the University of Arkansas at Monticello in 2020 and a Master of Science in Healthcare Administration from the University of Arkansas – Fort Smith in 2022. I am a Certified Healthcare Financial Professional through the Healthcare Financial Management Association and was previously a Certified Specialist Accounting and Finance.

4. I am familiar with Defendants’ plan to replace the 340B program’s current discount model with a rebate program starting on January 1, 2027, for twenty-five popular drugs. On April 20, 2026, DCMC submitted a comment letter to Defendant Engels in response to Defendant Health Resources and Services Administration’s (“HRSA”) Request for Information regarding a 340B rebate model, urging HRSA to abandon the rebate model and pursue deduplication through alternative mechanisms.¹ HRSA nonetheless announced the program in a notice published on August 3, 2026 (the “Notice”),² and on October 1, 2026, it published the rebate plans it had approved for ten manufacturers covering eighteen drugs (the “Approved Plans”).³ I have reviewed the Notice and the relevant plans. I also know the harm that this rebate program will cause DCMC if it goes into effect.

DCMC Provides Vital Services to a Vulnerable Population

5. DCMC opened to the public on May 4, 1958. We operate a twenty-five bed Critical Access Hospital in Fordyce, Arkansas, the seat of Dallas County, a town of just under 3,400 people. We commonly treat patients from Princeton, Tulip, Dalark, Sparkman, Carthage,

¹ Letter from Dallas Cnty. Med. Ctr. to Thomas J. Engels, Adm’r, Health Res. & Servs. Admin. (Apr. 20, 2026), HRSA-2026-0001-2261.

² 91 Fed. Reg. 48,883 (Aug. 3, 2026).

³ The Approved Plans are posted on HRSA’s website. *See* Health Res. & Servs. Admin., *340B Rebate Model Pilot Program*, <https://www.hrsa.gov/opa/340b-model-pilot-program> (last visited Oct. 5, 2026).

Farindale, Thornton, Bearden, Hampton, New Edinburg, Tinsman, Rison, and Kingsland. DCMC remains the largest employer in the county, which is known for its timber, farming, and railroad industries.

6. DCMC serves an elderly, low-income, rural population. Dallas County has been designated a medically underserved area by Defendant HRSA.⁴ The median income in Fordyce is nearly forty percent below the Arkansas state median.⁵ Just eleven percent of Fordyce residents hold a bachelor's degree or higher, more than fifty percent are not in the labor force, and over thirty percent have a disability.⁶ Approximately twenty-seven percent of DCMC's patient care is paid for by Medicare or Medicaid.

7. DCMC operates a Level IV Trauma Center and a twenty-four-hour emergency room. We are stroke-certified and have been recognized for our wound care services. We also offer an intensive outpatient psychiatric program, infusion services, radiology, outpatient therapy, and laboratory services, and we operate two rural health clinics.

8. Access to care remains a substantial challenge in Dallas County, despite our efforts. There is no mental health counseling available anywhere else in the entire county. The closest oncologist is an hour's drive each way. The nearest grocery store, outside of the small one here in town, is thirty miles away. Many of our patients do not have reliable private transportation, which makes traveling to obtain healthcare services a real barrier. Given the vital and irreplaceable services we provide, DCMC has been designated by Defendant Department of

⁴ Health Res. & Servs. Admin., *MUA Find*, <https://data.hrsa.gov/topics/health-workforce/shortage-areas/mua-find> (last visited Oct. 5, 2026).

⁵ U.S. Census Bureau, *Fordyce, AR*, https://data.census.gov/profile/Fordyce_city,_Arkansas?g=160XX00US0524220 (last visited Oct. 5, 2026).

⁶ *Id.*

Health and Human Services as an “Essential Community Provider” serving primarily low-income and medically underserved populations.⁷

9. DCMC is a county entity. Our goal is not to make a profit, but we must maintain operating capital to stay open and prevent patients from losing access to care. Our purpose is the same as that of the 340B program, to stretch scarce resources as far as possible so that we can reach more patients and provide more comprehensive services.

DCMC’s Financial Condition Leaves No Margin for New Costs

10. DCMC is in a delicate financial position. Our margin for 2026 is approximately 4.4 percent of our overall revenue, and we have approximately 111 days of cash on hand. Post-pandemic staffing shortages, increased supply costs, and diminished reimbursement from insurers, including Medicaid and Medicare Advantage, drive these decreasing margins. We operate on margins typical of the rural hospital sector.

11. Delayed payments to vendors have in some cases increased our interest costs and caused us to forgo early-payment discounts.

340B Savings Fund DCMC’s Service Lines, Facilities, and Staffing

12. DCMC has participated in the 340B program since August 2010. For the fifteen years since, the savings that program generates have been an indispensable component of our ability to operate as a Critical Access Hospital serving this community. In 2025, we filled 4,316 prescriptions through the program and realized net savings of \$1,790,587. Based on actual claims for January through June 2026, annualized, we expect to fill 3,954 prescriptions this year and realize net savings of approximately \$1,016,792.

⁷ Ctrs. for Medicare & Medicaid Servs., *HHS Rolling Draft Essential Community Provider (ECP) List for the Federally-facilitated Marketplace*, <https://data.healthcare.gov/rolling-draft-list> (last visited Oct. 5, 2026).

13. Our 340B savings are incorporated into our overall operating budget and have enabled us to expand service lines. We recently opened a telehealth clinic for oncology patients, created an intensive outpatient psychiatric program for seniors, expanded provider staffing in both of our primary care outpatient clinics, provided staff training for our electronic medical record, and began developing an infusion program. Before the telehealth oncology clinic, cancer patients in Dallas County had to drive over two hours round trip to see their physician.

14. DCMC policy is to provide healthcare services regardless of a patient's ability to pay, and the 340B program funds the dedicated financial assistance program through which we implement that policy.

15. The 340B program has also allowed DCMC to complete critical maintenance and to recruit and retain staff. For example, the roof on our nearly seventy-year-old building had fallen into such disrepair that staff had to place buckets and cookware around the hospital to catch leaks when it rained; using 340B savings, we replaced the roof without taking on debt in 2024. We used 340B savings to complete a substantial maintenance project on our outpatient therapy building, and those savings also allow 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.

The Maximum Fair Price Is Already Eliminating These Savings

16. Defendants propose a rebate mechanism at a time when DCMC's 340B savings are already declining sharply. In the first quarter of 2026 alone, approximately 33.5 percent of DCMC's would-be 340B savings on the selected drugs were eliminated by the Maximum Fair Price program. That is the principal reason our annual 340B savings are on course to fall by forty-three percent this year.

DCMC Built Its Operations in Reliance on the Upfront Discount Model

17. DCMC designed its pharmacy operations, its wholesaler arrangements, its third-party contractual relationships, and its long-term financial planning in reliance on the upfront discount model that has governed the 340B program since its inception. Those reliance interests are real and material, and a fundamental shift to a rebate mechanism would disrupt them in ways the proposed pilot has not accounted for. The mere existence of statutory authority to permit rebates does not make this change reasonable, particularly where Defendants have not quantified any purported problems with the upfront discount model.

DCMC Cannot Float the Wholesale Acquisition Cost of the Rebate Program Drugs

18. DCMC dispenses ten of the eighteen drugs included in Defendants' rebate program.⁸ Those ten drugs generate the majority of our 340B savings. In 2025, they accounted for approximately 64 percent of DCMC's total 340B savings. Defendants' rebate mechanism therefore reaches the majority of our 340B program.

19. Applying our 2025 claims data to these ten drugs, the acquisition cost to DCMC under an upfront discount model would be approximately \$163,000 in 2027. Under Defendants' rebate model, however, the WAC cost on those same drugs is a tenfold increase—approximately \$1.66 million. The cumulative working capital DCMC would be required to float throughout 2027 to drug manufacturers is therefore approximately \$1.5 million.

20. For a Critical Access Hospital of our size, \$1.5 million diverted to manufacturers for rebate processing is simply not possible without borrowing, with the associated interest expense and debt service, or through offsetting reductions in services. Adding a rebate

⁸ Those drugs are: Eliquis, Farxiga, Januvia, Jardiance, Linzess, Vraylar, Trelegy Ellipta, Janumet, Tradjenta, and Breo Ellipta.

mechanism therefore would tie up operating capital we need for patient care and add staffing and vendor costs, even as our 340B savings keep shrinking.

21. A rebate mechanism would effectively require DCMC to provide drug manufacturers with interest-free financing while we await the statutory discount to which we are entitled. Even a ten-day manufacturer payment window does not eliminate that exposure because certain of our wholesalers require daily payment.

The Ten-Day Rebate Window Does Not Prevent the Float, and Manufacturers Face No Mandatory Consequences When They Fail to Timely Pay Rebates

22. There is another problem that compounds my cash flow concerns. Our wholesaler arrangements are configured for 340B acquisition pricing, not wholesale acquisition cost. Moving the selected drugs to wholesale acquisition cost materially increases our monthly invoice exposure, which puts us in danger of exceeding our credit limits and preventing us from providing those drugs to patients at all.

23. Ahead of the 2026 pilot, our wholesalers were not prepared to extend the credit limits DCMC needed on its 340B accounts to operationalize even the partial rebate program. When credit limits are exceeded, wholesalers stop fulfilling drug orders. That does not halt the 340B program only for the drugs in the pilot. It halts the 340B program for every 340B product DCMC purchases.

24. Defendants' program would also put the decision whether DCMC receives its statutory discount under the control of the drug companies themselves. Our contract pharmacies dispense all ten of the rebate program drugs that DCMC dispenses. For the past six years, manufacturers have pursued unilateral policies restricting 340B pricing at contract pharmacies, and those restrictions remain the subject of ongoing litigation and regulatory dispute. Defendants' rebate model would put those same manufacturers in charge of adjudicating rebate

claims on the very dispenses they have spent six years attempting to exclude from the 340B program. I do not believe the companies that have worked that long to deny us the discounts on these prescriptions can be relied upon to police our claims to them.

25. Moreover, Defendants do not intend to publish an actual dispute resolution process until approximately thirty days after the rebate program takes effect, and I understand that covered entities will be required to challenge rebate denials with Beacon and the drug companies themselves. Because Defendants' ability to take action against drug companies that fail to pay timely rebates or inappropriately deny rebates is purely discretionary, I fear drug companies will face no penalty for missing the ten-day window or improperly denying a rebate. 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.

DCMC Does Not Have the Staff or Systems to Comply

26. DCMC administers the current 340B program with a single employee. HRSA estimates that its rebate program will require merely five hours of work per covered entity per week and that additional staffing will in many cases be unnecessary.⁹ In our comment letter, we estimated that Defendants' rebate mechanism will require approximately ten hours per week, twice HRSA's figure, and the Approved Plans have only added to that work.¹⁰ For a Critical Access Hospital with our staffing profile, that means we will likely need to divert a former pharmacy technician from her core responsibilities of community education and outreach. In a county where DCMC staff attends festivals and local events because that is how many residents

⁹ 91 Fed. Reg. 35,989, 35,990 (June 15, 2026).

¹⁰ Letter from Dallas Cnty. Med. Ctr. to Thomas J. Engels, HRSA-2026-0001-2261, at 4.

learn what care is available to them, absorbing the work with a current employee does not make it free. It simply makes the loss hard to find on a balance sheet.

27. Administration of this rebate mechanism divides into two parts, neither of which can be automated the way HRSA assumes. The first is data submission. The fields for our contract pharmacy claims are already collected in the ordinary course of business, but they reside in two different third-party administrator systems. The fields required for medical claims are not as readily available, and assembling them across our electronic medical record and our billing systems is substantially more complicated and will require manual compilation.

28. The second part, reconciliation, I expect to be more costly and burdensome. Because the 340B program has always operated under an upfront discount mechanism, we have never had to reconcile incoming rebates. Unlike an upfront discount, a rebate requires DCMC to match payments received weeks or months later to individual drug purchases and claims; identify claims for which rebates are missing, delayed, denied, or underpaid; investigate discrepancies between our records and manufacturers' determinations; correct or resubmit claims where appropriate; and pursue unresolved amounts with manufacturers or their vendors. Once a payment arrives, we cannot simply treat it as undifferentiated revenue. We must determine which underlying 340B transactions the payment covers, match those transactions to our own purchasing and claims records, and then allocate the payment to the appropriate internal accounts, facilities, departments, pharmacies, and cost centers. These are not merely bookkeeping formalities. They require coordination among pharmacy, finance, accounting, revenue-cycle, and information-technology personnel and, in many cases, manual investigation that no technology available to DCMC can perform for us.

29. The Approved Plans compound that reconciliation burden, because there is no single set of rules to reconcile against. For example, under the Notice, a manufacturer may refuse a rebate on the ground that it duplicates the maximum fair price only if it supplies “rationale and specific documentation” for doing so.¹¹ The Approved Plans, however, take inconsistent positions on how that overlap is handled. Certain manufacturers have reserved the right to deny the 340B rebate outright whenever the drug also carries a maximum fair price. Other manufacturers have committed to pay the 340B rebate in full and to recover the overlap by reducing the maximum fair price refund processed through the Medicare Transaction Facilitator. Thus, two identical claims may yield a payment from one company and a denial from another—and the manufacturers allow themselves room to switch approaches after the program is underway. The one DCMC employee who administers our 340B program would have to track each manufacturer’s policy, watch for revisions, and evaluate every denial under whichever standard happened to apply.

30. The 45-day submission deadline creates even more work. Any claim DCMC files more than 45 days after the drug is dispensed will be rejected, and the Notice requires a showing of “extenuating circumstances” to receive an extension.¹² Each time a claim falls outside the 45-day window, we would have to write up the circumstances by hand and ask that an exception be granted “on a case-by-case basis.” The Notice does not say what counts as extenuating, how quickly a request will be decided, or whether the deadline is tolled while the request is under review. Because DCMC must compile its medical claims data manually from our electronic

¹¹ 91 Fed. Reg. at 48,903.

¹² *Id.* at 48,902.

medical record and billing systems, a hard 45-day cutoff means a genuine risk that we will forfeit discounts the statute entitles us to receive.

31. Separate from those recurring costs, we would incur one-time startup costs of approximately \$8,000 to build the claims submission and reconciliation infrastructure a rebate model requires. Those startup costs are sunk regardless of whether Defendants' so-called pilot succeeds.

32. We are preparing for January 1, 2027, as best we can, and so are our vendors. But taking into account the time required to build claims submission and reconciliation processes that do not exist today, and how much about the Notice and the Approved Plans remains unclear, I do not believe DCMC can be prepared to implement Defendants' rebate program by January 1, 2027.

The Rebate Program Has Harmed DCMC

33. If Defendants' rebate mechanism goes into effect, we would be at risk of cutting unprofitable service lines, such as our telehealth oncology clinic, which would return Dallas County cancer patients to a two-hour round trip for every appointment. Another at-risk program is our intensive outpatient psychiatric program for seniors, and there is no mental health counseling anywhere else in this county.

34. Because of the uncertainty surrounding the future of our 340B savings, DCMC has also placed all non-revenue-generating projects on temporary hold. Those include the maintenance and access projects we had planned before the first rebate program was announced: at least \$35,000 in needed boiler room maintenance, a wheelchair-accessible shower the hospital still lacks, an employee daycare in a repurposed nursing home that would help us recruit working

mothers, and a telehealth clinic in a local school to reach children who lack access to care. All of them have remained on hold since last year due to the possibility of Defendants' rebate program.

35. Ultimately, the financial pressure from Defendants' rebate mechanism could force DCMC to leave the 340B program altogether.

36. DCMC exists because there is no other hospital in Dallas County. Every dollar Defendants' rebate mechanism would divert from patient care—to float drug companies, to chase rebates we are already owed, to staff an administrative apparatus that treats no one—is a dollar taken from a community that has no alternative.

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

Executed this 8th day of October, 2026 at Fordyce, Arkansas.

/s/Trapper Denton
Trapper Denton