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. 26-cv-_____

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 <u>*their own*</u> 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 <u>*no value at all*</u> 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. <u>Non-economic costs</u>. "'[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.

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Respectfully submitted,

/s/ _____

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**Pro hac vice application forthcoming.*