UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER, Plaintiffs, v. ROBERT F. KENNEDY, JR. Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA, Defendants.	Case No. **MOTION FOR TEMPORARY RESTRAINING ORDER WITH INCORPORATED MEMORANDUM OF LAW** **REQUEST FOR IMMEDIATE RELIEF**

INTRODUCTION

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

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

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

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

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

BACKGROUND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

LEGAL STANDARD AND REVIEWABILITY

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

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

ARGUMENT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

---

never appeared elsewhere in the *Federal Register*.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

resources away from their core mission or abandon vital programs. *See, e.g., Somerville Pub. Schs. v. McMahon*, 139 F.4th 63, 75 (1st Cir. 2025) (irreparable harm where "the challenged actions would jeopardize [plaintiffs'] ability to proceed with their programs"); *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 9 (D.C. Cir. 2016) (similar); *Mass. Fair Hous. Ctr. v. U.S. Dep't of Hous. & Urb. Dev.*, 496 F. Supp. 3d 600, 611 (D. Mass. 2020). That is exactly what will happen here. As a unanimous Supreme Court explained, "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022). The diversion of that funding, which is *already occurring* in advance of January 1, irreparably harms those valuable services and that mission.

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

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

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

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

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

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

CONCLUSION

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

Dated: December 1, 2025

Respectfully submitted,

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

Karen Dunn*
L. Rush Atkinson*
Lyle W. Gruby*
Jenifer N. Hartley**
Dunn Isaacson Rhee LLP
401 9th Street, NW
Washington, DC 20004
(202) 240-2900
kdunn@dirllp.com
ratkinson@dirllp.com
lgruby@dirllp.com
jhartley@dirllp.com

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