UNITED STATES DISTRICT COURT

DISTRICT OF MAINE

AMERICAN HOSPITAL ASSOCIATION, et al.,	)	
Plaintiffs,	)	
v.	)	No. 2:25-cv-00600-LEW
ROBERT F. KENNEDY, JR., SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,	)	
Defendants.	)	

ORDER ON MOTION FOR PRELIMINARY INJUNCTION

Like the old adage, "crawl, walk, run," the Administrative Procedure Act's (APA) arbitrary and capricious standard imposes vanishingly minimal requirements that a federal agency must satisfy before launching a new program or policy. Those minimal requirements are simply that the agency action be reasonable and reasonably explained. Thus, before a new program that affects the rights and privileges of the public can be up and running, the agency must undertake the basic task of developing a contemporaneous record of the relevant factors it considered and provide a reasoned explanation for its course of action.

This axiomatic principle of administrative law is no less applicable in the context of administering complex federal drug pricing laws. With the laudable goal of resolving competing congressional directives to offer price concessions to certain "covered entities"

under both the longstanding 340B Program and the nascent Inflation Reduction Act's Drug Price Negotiation Program, the Health Resources and Services Administration (HRSA) plans to launch a hastily assembled 340B Rebate Model Pilot Program (the Rebate Program) on January 1, 2026, to "deduplicate" these price concessions. Although the HRSA is empowered by statute to achieve the de-duplication objective through a rebate model, and although it applies to only a subset of drugs sold to 340B covered entities, it marks a departure from the Agency's decades-long practice of requiring upfront discounts on 340B eligible drugs, and the Agency's roll out has involved a rather threadbare administrative record that likely fails to consider and reasonably explain the impact of a rebate model on 340B hospitals, who rely on upfront price concessions to stretch few resources as far as possible to serve rural and poor communities. The APA likely requires more from Defendants. For the reasons explained below, Defendants are preliminarily enjoined from implementing the Rebate Program pending further order.

BACKGROUND

In 1990, Congress created the Medicaid drug pricing rebate program to lower the cost of pharmaceuticals reimbursed by the States under Medicaid. The program conditions Medicaid and Medicare Part B coverage for a pharmaceutical companies' (hereafter "manufacturers") products on the manufacturer's participation in rebate agreements with the Secretary of Health and Human Services (HHS). By participating, manufacturers are contractually bound to pay rebates to state Medicaid programs at the statutorily determined price for certain drugs.

In 1992, Congress separately enacted Section 340B of the Public Health Service Act to assist "covered entities" (i.e., safety-net healthcare providers serving the most vulnerable populations) with their drug-acquisition costs. Pub. L. No. 102-585 § 602 (1992). Under Section 340B, manufacturers enter into pricing agreements with the Secretary in exchange for having their drugs covered by Medicaid and Medicare Part B. 42 U.S.C. § 1396r-8(a)(1); *id.* § 256b(a). In these 340B agreements, manufacturers agree to provide upfront discounts to 340B covered entities, such as Plaintiffs. Critical to understanding this unfolding narrative is the fact that Medicaid and the 340B Program are different programs imposing different pricing constraints on participating manufacturers.

Since the inception of the 340B drug pricing program, HRSA has required drug manufacturers to provide 340B discounts at the time of sale, colloquially called "upfront discounts," *id.* § 256b(a)(1); Section 602 Guidance, 58 Fed. Reg. 27289, 27291-92 (May 7, 1993), in order to "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive resources." H.R. Rep. No. 102-384(II) at 12 (1992). As recently as last year, HRSA rejected several manufacturers' proposal to switch to a rebate model, taking the position that an upfront discount model is superior and the switch would be disruptive to the operation of the 340B program. *See* Compl. ¶¶ 43–46, 48; Ex. 1 at -66; Ex. 4 at -292; Ex. 5 at -342.

However, in the state-administered Medicaid context, a rebate model is standard. In the Inflation Reduction Act of 2022 (IRA), Congress established the Medicare Drug Price Negotiation Program, which authorizes the Secretary to negotiate a "Maximum Fair Price" (MFP) that Medicare pays for certain eligible drugs. Inflation Reduction Act of

2022, Pub. L. No. 117-169, 136 Stat. 1818; U.S.C. §§ 1320f(a), 1320f-1(b), (d), (e). State Medicaid programs generally pay more than the MFP when administering Medicaid but receive a rebate from manufacturers to ensure that they pay only the MFP on behalf of qualifying patients.

Because several drugs are subject to both the Medicaid MFP and the 340B price concession, there is the potential (commonly realized) that manufacturers are mistakenly subjected to duplicative price concessions when a MFP rebate is claimed for a drug that a covered entity purchased at the 340B price.[1] Where MFP and 340B price concessions overlap, the IRA's "nonduplication" provision requires drug manufacturers to provide the lower of the 340B ceiling price and the MFP to covered entities, but not both. 42 U.S.C. § 1320f-2(d). There does not appear to be any dispute that a well-designed program would avoid duplication, and the parties generally refer to this objective as the "de-duplication" objective.

On July 31, 2025, HRSA announced the 340B Rebate Program, which would allow certain drug manufacturers to charge their drug's wholesale price to 340B covered entities and later issue a rebate to reflect the statutorily required discount price and achieve the de-duplication objective. *See* Press Release, HRSA, HRSA Announces Application Process for the 340B Rebate Model Pilot Program and Request for Public Comment (July 31,

[1] Section 340B covered entities also serve Medicaid participants and may dispense drugs to Medicaid participants that they purchased at the 340B discount price. When a Medicaid program seeks and receives the MFP rebate on these prescriptions, manufacturers will have provided a duplicative discount. Such loses spread across the entire 340B network add up to substantial sums of money that should have been realized by the manufacturers rather than the 340B entities or state Medicaid programs.

2025), https://www.hrsa.gov/about/news/press-releases/rebate-model-pilot-program (last visited Dec. 29, 2025). The next day, August 1, 2025, HRSA published notice of the new program in the Federal Register, inviting drug manufacturers to submit applications to participate. Rebate Program Application Notice, 90 Fed. Reg. 36163 (Aug. 1, 2025). HRSA's Notice explained the purpose of the Rebate Program was to address concerns over duplicate discounting by drug manufacturers attempting to ensure that covered entities receive only the 340B upfront discount or the IRA's Medicaid MFP, but not both. Corr. Rebate Program Application Notice, 90 Fed. Reg. 38165 (August 7, 2025). Between October 30 and November 14, 2025, HRSA approved rebate applications from nine eligible drug manufacturers for ten covered drugs. Although the applications concern only ten covered drugs, the anticipated program will be implemented across the entire population of 340B covered entities, all of whom will need to free up money to pay the much higher wholesale drug prices and implement new internal processes to pursue the rebates.[2]

On December 1, 2025, the American Hospital Association (AHA) and the Maine Hospital Association (MHA), along with several of AHA's and MHA's members, (collectively, "Plaintiffs") filed their Complaint (ECF No. 1) and Motion for Temporary Restraining Order (ECF No. 3), seeking to enjoin implementation of the Rebate Program.

[2] In addition to the preceding background concerning the legislative landscape and the deduplication effort, Plaintiffs' claims rely on a collection of facts associated with the nature and quality of the administrative record and the nature and quality of the harms that will be visited upon them by the Rebate Program. I relate those particularized facts in the preliminary injunction discussion that follows.

Plaintiffs allege that Federal Defendants'[3] establishment and implementation of the 340B Rebate Program violates the Administrative Procedure Act (APA) and ask this Court to declare the program unlawful under § 706 of the APA. Compl. ¶¶ 52-62, 130-175. Because the parties have all been heard on the propriety of emergency injunctive relief, including at a December 19, 2025 hearing, I construe Plaintiffs' Motion as a request for a preliminary injunction rather than a temporary restraining order. The parties have conferred and agree to proceed on this basis. Opp'n at n.1 (ECF No. 75).

DISCUSSION

The parties' briefs raise the issues of justiciability as well as the question of whether Plaintiffs can meet all four of the preliminary injunction factors. I therefore begin this discussion with the issue of whether Plaintiffs' claims present a justiciable controversy (they do) before turning to whether preliminary injunctive relief is warranted. Because I conclude that relief is warranted on the record presently before me, I necessarily conclude with a discussion of the appropriate nature and scope of relief.

A. JUSTICIABILITY

Before reaching the merits, I first briefly address Defendants' two arguments against judicial review: HRSA's promulgation of the Rebate Program is not final agency action and the decision to effectuate 340B prices through rebates is committed to agency

[3] Robert F. Kennedy, Jr. in his official capacity as Secretary of the U.S. Department of Health and Human Services; Thomas J. Engels, in his official capacity as Administrator of Health Resources and Services Administration (HRSA); the U.S. Department of Health and Human Services (HHS); and the United States of America. *Compl.* ¶¶ 19-23.

discretion by law. I reject both arguments because they mischaracterize the nature of Plaintiffs' claims. First, Defendants pettifog on the distinction between their general authority to administer a rebate model program and the approved applications that comprise the Rebate Program itself. As Defendants concede, however, the application approvals do constitute final agency action, which by their nature are reviewable under the APA. *See* 5 U.S.C. § 704. Second, Defendants maintain that because the Public Health Service Act provides the Secretary with the discretion to effectuate the 340B ceiling prices through either rebates or discounts, without a benchmark against which to judge the Secretary's choice, Congress committed that decision to the Secretary alone and the judicial branch must avert its gaze, judicial review being unavailable. Opp'n at 11-13. According to Defendants, that unreviewable discretion extends to the Agency's decision to approve the nine drug manufacturers' applications to participate in the Rebate Program. *Id.*

Assuming without questioning the Secretary's discretion to choose between discounts and rebates to effectuate 340B price concessions, see *Webster v. Doe*, 486 U.S. 592 (1988), the Agency's approval of the drug manufacturers' individual applications is reviewable under the APA. Judicial review of the approvals, including the scope of the resulting program and the expedited pace of its implementation, is entirely consistent with the APA's strong presumption of judicial review, and the longstanding practice of narrowly reading the agency discretion exception "to those rare administrative decisions traditionally left to agency discretion." *Dept. of Homeland Security v. Regents of the Univ. of Cal.*, 591 U.S. 1, 17 (2020) (citations omitted). Accordingly, judicial review of the Agency's

approval of the nine applications to participate in the "Rebate Program," is appropriate under the APA.

B. THE PRELIMINARY INJUNCTION FACTORS

The extraordinary and drastic remedy of a preliminary injunction requires a showing of four elements: (1) substantial likelihood of success on the merits; (2) a high likelihood of irreparable harm if injunctive relief is not granted; (3) a balance of equities tips in the movant's favor; and (4) the injunctive relief is in the public interest. *See Voice of the Arab World, Inc. v. MDTV Med. News Now, Inc.*, 645 F.3d 26, 32 (1st Cir. 2011) (citing *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). The last two factors "merge when the Government is the party opposing the preliminary injunction." *Nken v. Holder*, 556 U.S. 418, 435 (2009). The most important of the four elements is the likelihood of success on the merits—which is considered the "sine qua non" of the inquiry. *Ryan v. U.S. Immigr. & Customs Enf't*, 974 F.3d 9, 18 (1st Cir. 2020) (quoting *New Comm Wireless Servs., Inc. v. SprintCom, Inc.*, 287 F.3d 1, 9 (1st Cir. 2002)).

As explained below, the anemic administrative record alone supports a conclusion that Plaintiffs have made a strong showing of likelihood of success, at least as matters stand today. Additionally, Plaintiffs' showing of economic impact and disruption to services is substantial and, paired with such a strong showing on the merits, sufficient to demonstrate irreparable injury. With these initial factors tilting the board decisively in Plaintiffs' direction, the remaining factors easily slide in Plaintiff's favor.

1. Likelihood of Success on the Merits

The APA's arbitrary-and-capricious standard requires that agency action be both reasonable and reasonably explained. "An agency's decision is arbitrary and capricious if the agency relied on improper factors, disregarded 'an important aspect of the problem, offered an explanation that runs counter to the evidence,' or when a reasonable explanation for the agency's decision cannot be discerned." *Gulluni v. Levy*, 85 F.4th 76, 82 (1st Cir. 2023) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)); *accord Melone v. Coit*, 100 F.4th 21, 29-30 (1st Cir. 2024). Judicial review under this standard is deferential, and a court may not substitute its own policy judgment for that of the agency. *State Farm*, 463 U.S. at 43. "A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *Federal Communications Comm'n v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021); *accord Fam. Plan. Assoc. of Me. v. U.S. Dept. of Health and Human Srvs.*, 466 F. Supp. 3d 259, 266-67, 269 (D. Me. 2020).

a. The administrative record

A significant flaw with Defendants' institution of the Rebate Program relates to the paucity of the administrative record. Defendants present for review a July 31, 2025 press release, an August 1, 2025 Federal Register Notice (correction issued August 7), the Agency website's FAQs, a letter to the Office of Management and Budget (OMB), and a few documents and correspondence related to HRSA's approval of AbbVie Inc.'s and Janssen Pharmaceuticals, Inc. and Janssen Biotech, Inc.'s applications to participate in the Rebate Program. To fill the yawning void in this administrative "record," Defendants also

offer as a load-bearing beam to carry the weight of their argument the Declaration of Chantelle Britton (ECF No. 75-1), Director of the Agency's Office of Pharmacy Affairs, which Defendants aver is permissible for the court to consider to "illuminate reasons obscured but implicit in the administrative record." Opp'n at 14 n.5 (quoting *Clifford v. Pena*, 77 F.3d 1414, 1418 (D.C. Cir. 1996)).

"It is a 'foundational principle of administrative law' that judicial review of agency action is limited to 'the grounds that the agency invoked when it took the action.'" *Regents of the Univ. of Cal.*, 591 U.S. at 20 (quoting *Michigan v. EPA*, 576 U.S. 743, 758 (2015)). And while an agency may later "elaborate" on those grounds, it "may not provide new ones." *Id.* at 21 (citing *Camp v. Pitts*, 411 U.S. 138, 143 (1973) (per curiam)). "In other words, an agency must stand by the reasons it provided at the time of its decision and cannot rely on post-hoc rationalizations developed and presented during litigation." *In re Fin. Oversight and Mgmt. Bd. for P.R.*, 37 F.4th 746, 761 (1st Cir. 2022); *see also Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 419 (1971); *State Farm*, 463 U.S. at 50.

Despite Defendants' representations to the contrary, the Britton Declaration largely presents post hoc rationalizations absent from the administrative record, precisely the non-cotemporaneous explanations excluded from consideration in APA challenges. *See Regents of the Univ. of Cal.*, 591 U.S. at 23; *Am. Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 539 (1981) ("the post hoc rationalizations of the agency . . . cannot serve as a sufficient predicate for agency action"); *Overton Park*, 401 U.S. at 419 (rejecting "litigation affidavits" from agency officials as "merely '*post hoc*' rationalizations"); *Cal.*

v. U.S. Dept. of Educ., 132 F.4th 92, 99 (1st Cir. 2025) (rejecting litigation affidavit's "newfound claim of clarity" as post hoc rationalization). To the extent that this tatty administrative record is ambiguous, I consider the Britton Declaration for clarity, but because the record is mostly silent on salient considerations that would guide any rational policy-making process, Director Britton's representations are, for the most part, of no use. *Clifford*, 77 F.3d at 1418.

Finally, amicus AstraZeneca Pharmaceuticals LP offered documents and correspondence related to HRSA's approval of its Rebate Program application. *See* Sky Adams Decl. (ECF No. 88-1). The vast majority of these documents are AstraZeneca's own, and though I appreciate that AstraZeneca is a beneficiary of the Rebate Program, its contributions do not constitute the administrative agency record. To the extent they include HRSA's own documents, it is curious why the Agency did not incorporate them into the administrative record, let alone submit them for consideration. In any event, information presented in this filing is at best circumstantial evidence of what the Agency might have considered, not evidence that it did. Moreover, the animating principle behind the prohibition of post hoc rationalization in APA cases is that democratically unaccountable federal agencies wielding executive power to carry out congressional objectives must do their own homework, build an administrative record, and then demonstrate the application of something resembling a thought process in regard to what the record contains (more on that to follow).

b. Failure to provide a reasonable explanation or address significant reliance interests

Plaintiffs allege Defendants' failure to address significant reliance interests is fatal to the Rebate Program. Specifically, Plaintiffs' point to Defendants' failure to even state how 340B entities' more than thirty-year reliance interests in a discount model weighs against the Rebate Program's de-duplication goal. Mot. at 11. Plaintiffs further assert Defendants have failed to meet the APA's requirement of a reasoned explanation for their policy shift because they fail to offer genuine justifications for why the Rebate Program as designed was necessary to achieve its de-duplication goal, what costs and benefits might be relevant, or how patients could be affected. *Id.* at 10.

Defendants counter that they did reasonably explain the policy change and consider reliance interests. In its August 7, 2025 Federal Register Notice, HRSA explained that the purpose and nature of the Rebate Program is based on feedback from drug manufacturers and covered entities about addressing the de-duplication problem and to test the merits and shortcomings of a rebate model. Opp'n at 14-15; Corr. Rebate Program Application Notice, 90 Fed. Reg. 38165 (Aug. 7, 2025). Defendants also maintain that they did consider these reliance interests, pointing to a Federal Register Notice acknowledging the "fundamental[ ] shift" a rebate model offers, and explaining that the Agency has limited the scope of the Rebate Program to a pilot covering only 2% of total drug sales in the 340B

program.[4] Opp'n at 15; Corr. Rebate Program Application Notice, 90 Fed. Reg. 38165 (Aug. 7, 2025); Britton Decl. ¶¶ 5, 22-25.

When an agency changes position on prior policy that has engendered serious reliance interests, it is arbitrary and capricious to ignore the facts and circumstances engendered by that prior policy. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009); *Smiley v. Citibank (S.D.) N.A.*, 517 U.S. 735, 742 (1996). In these circumstances, "agencies are free to change their existing policies as long as they provide a reasoned explanation for the change, display awareness that they are changing position, and consider serious reliance interests." *Food and Drug Admin. v. Wages & White Lion Invs., LLC*, 604 U.S. 542, 568 (2025) (citations and quotations marks omitted). In considering reliance interests the agency must "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.

At the threshold, Defendants concede Plaintiffs' "decades of industry reliance" in the 340B discount model is significant. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016). What matters then is simply whether the Agency (1) reasonably explained its change in position, (2) displayed awareness of its change, and (3) considered Plaintiffs' serious reliance interests. It is clear the Agency has displayed awareness that the Rebate

[4] Plaintiffs dispute Defendants' characterization of the Rebate Program as "limited" or a "pilot." According to Plaintiffs, at least in its current iteration, the Rebate Program is a "pilot" in name only because it applies nationwide, mandating approximately 14,600 340B entities to participate in the Rebate Program for ten of the most commonly used drugs. *See* Compl. ¶¶ 7, 56; Reply at 9.

Program constitutes a shift in policy, and Plaintiffs do not contest this factor. On the remaining two factors, I find Plaintiffs are likely to succeed on the merits of their reliance interest claim but that their reasoned explanation claim is a closer call that I need not wade into at the preliminary injunction stage because Defendants' failure to address reliance interests is fatal to a January 1, 2026 rollout of the Rebate Program.

First, there is no evidence in the administrative record that Defendants considered Plaintiffs significant reliance interests. Defendants rely on a single sentence in their August 7, 2025 Federal Register Notice acknowledging "rebate models could fundamentally shift how the 340B Program has operated for over 30 years." Opp'n at 15 (quoting Corr. Rebate Program Application Notice, Fed. Reg. 38165 (August 7, 2025)). This is problematic for several reasons. First, the sentence does not support Defendants' contention that they considered 340B entities' reliance interests. Noting a change in a program's operation is not the same as recognizing that the change will impact 340B entities in detrimental ways. Furthermore, it does not evidence that HRSA weighed any reliance interest against the competing de-duplication policy concern or the proposed de-duplication approach favored by the participating manufacturers. *Regents of the Univ. of Calif.*, 591 U.S. at 33. Indeed, the record's silence on reliance interests reverberates throughout HRSA's approval of all nine Rebate Program applications. Defendants are left only to rely on post-hoc rationalizations in the Britton Declaration, which cannot substitute for the contemporaneous record. Accordingly, without anything more from the administrative record, the Britton Declaration does not "merely illuminate" the reasons "implicit in the administrative record," but rather offers impermissible non-contemporaneous explanations

precluded from consideration. *See U.S. Dept. of Educ.*, 132 F.4th at 99 ("this newfound claim of clarity approaches the sort of 'post hoc rationalization' that we cannot allow").

Although a closer call, it stands to reason Defendants have also failed to provide a reasoned explanation for the Rebate Program, at least in regard to design components. Arbitrary and capricious review is a minimal standard, and a reviewing court is only to assess "whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Overton Park*, 401 U.S. at 416. Plaintiffs' allegations that the Rebate Program lacks "genuine justifications," Mot. at 10, seem to invite me to make a policy judgment in place of the Agency, something I cannot do. *State Farm*, 463 U.S. at 43. Defendants explain that the Rebate Program is based on resolving the deduplication problem, and it is not the provenance of the courts to second guess that determination, only to probe whether the Agency's consideration and explanation remained "within a zone of reasonableness." *Prometheus Radio Project*, 592 U.S. at 423. I agree with Defendants' explanation of my limited role regarding review of agency action, but exercising deference would be manifestly easier if there was any meaningful administrative record for me to review. It seems impossible to conclude that HRSA reasonably explained its policy change when the administrative record is entirely silent on a relevant factor—the 340B hospitals' reliance interests. And given the Agency's failure to consider significant reliance interests, I cannot say that the administrative record necessarily offers a reasonable explanation for the Defendants' establishment of the Rebate Program, though I need not wade into this at the preliminary injunction stage because Defendants' failure to address reliance interests is alone fatal to the Rebate Program.

c. Failure to consider relevant costs

Plaintiffs argue that Defendants ignored the costs associated with the Rebate Program, including administrative costs, the costs of paying full price for covered drugs and awaiting a rebate (sometimes referred to as "floating" costs), and other non-monetary costs. Pls.' Mot. at 12-15. Defendants counter they did consider these costs, citing the August 7, 2025 Federal Register Notice, their Emergency Letter to OMB, and the Britton Declaration. Opp'n at 17-18. Defendants aver the Agency's determination that the benefits of the Pilot Program outweigh those costs is entitled to substantial deference. *Id.* at 18.

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 Co. v. U.S. Dept. of Com.*, 60 F.4th 956, 973 (5th Cir. 2023) (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.* "Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages and the disadvantages of agency decisions." *Michigan*, 576 U.S. at 753.

Fatal to Defendants' counterargument is their own admission that the Agency is "currently examining" administrative costs. Opp'n at 17 n.7. In other words, Defendants have not yet considered an important aspect of the problem, rather they are still evaluating administrative costs. Specifically, while in its letter to OMB, the agency initially estimated $200 million in compliance costs to 340B entities, the agency is still reviewing public "comments alleging an under-estimation of administrative costs . . . and will [later] address

those concerns." Britton Decl. ¶ 35 (citing Paperwork Reduction Act Notice, 90 Fed. Reg. 44197 (Sep. 12, 2025)). This failure to consider administrative costs before approving the manufacturers' applications under the Rebate Program is fatal under the APA. *Michigan*, 576 U.S. at 759-60.

The administrative record is also silent on the cost of floating the full price of covered drugs until 340B entities receive their rebate. Defendants only response is more post hoc rationalization in the Britton Declaration that the Agency's decision to limit the scope of the Rebate Program to ten drugs and require drug manufacturers to pay rebates within ten calendar days demonstrate their consideration of the burden that will be placed on 340B entities to float upfront costs. Britton Decl. ¶¶ 5, 27-30, 34, 38, 41. Similarly, the non-monetary costs to 340B entities, including the impact these additional prices might have on their long-term viability represents another unaddressed "important aspect of the problem." *State Farm*, 463 U.S. at 43.

Defendants' call for judicial deference on this determination rings hollow. Their bald assertion that the benefits of the Rebate Program outweigh any negative impact associated with floating the full price of covered drugs, Britton Decl. ¶¶ 34, 41, smacks of "clairvoyance" rather than the kind of "exercise in logic" deserving of judicial deference. *Fox Television Stations*, 556 U.S. at 521. Particularly as here where 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. *FCC v. Nat'l Citizens Comm. for Broad.*, 436 U.S. 775, 815 (1978). Even supposing it were, Defendants make no argument that such a determination is within their expertise aside from the naked claim that we should

simply take their word for it. Furthermore, any colorable argument to that effect is belied by the absence of any evidence in the administrative record about upfront costs, particularly considering the numerous public comments estimating hundreds of millions of dollars in additional costs to 340B hospitals they might struggle to pay under a rebate model.[5] *See, e.g.*, Austin Decl. ¶¶ 13-14 (ECF No. 4); Brown Decl. ¶¶ 14, 20 (ECF No. 5); Fadale Decl. ¶¶ 14-15, 21 (ECF No. 6).

For the foregoing reasons, the administrative record's silence on Defendants' efforts to consider and reasonably explain the relevant costs associated with the Rebate Program offer independent grounds to conclude that Plaintiffs have demonstrated a likelihood of success on the merits.

d. Other relevant factors and pertinent aspects

Plaintiffs also assert that Defendants' failure to address public comments, less costly alternatives, and issues with the electronic database used to collect and store rebate claims data and the rebate dispute resolution mechanism also invalidate the Rebate Program. Defendants maintain they are not required to respond to public comments and that they did consider these aspects of the problem.

In establishing and implementing the Rebate Program, Defendants were not required to respond to public comments. *Cf.* 5 U.S.C. § 553; *Perez v. Mortgage Bankers Assoc.*, 575 U.S. 92, 96 (2015). To the extent the public comments highlighted an

[5] I do not mean to suggest that Defendants must weigh the burdens imposed on each and every entity that makes up the Public Health Service. However, the fact that the "pilot" program impacts them all calls for something more than casual indifference to localized impacts.

important aspect of the problem, they may be evidence of an agency's failure to reasonably explain its position, which I already addressed in relation to reliance interests and costs. *State Farm*, 463 U.S. at 43. Plaintiffs' arguments concerning less costly alternatives, the dispute resolution mechanism, and the rebate database all venture into the territory of asking for a policy judgment against the Agency. *Id.* In other words, digging into these arguments likely requires policy considerations about the nature and scope of the Rebate Program and the effectiveness of some of its component parts. Considering that Plaintiffs are likely to succeed on the merits without wading into these trickier issues, my analysis of the merits stops here.

2. Irreparable Harm

Plaintiffs allege irreparable harm for the costs they will incur from the Rebate Program between floating the upfront costs of covered drugs (far in excess of the costs they will ultimately be responsible for), hiring additional staff to process and track rebate claims, and cutting back or altogether abandoning certain programs and services. Mot. at 16-19. Defendants contend Plaintiffs' costs associated with the Rebate Program are not irreparable because they are speculative, mitigated by the benefits they will receive from the Rebate Program, and impermissibly rely on alleged harm to third parties. Opp'n at 19-22.

Irreparable harm is "a cognizable threat" of "a substantial injury that is not accurately measurable or adequately compensable by money damages" to the movant. *Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 102 F.3d 12, 19 (1st Cir. 1996). Although it need not "be fatal to [the movant's] business," *id.* at 18, it "must be grounded on something more than conjecture, surmise, or a party's unsubstantiated fears of what the

future may have in store." *Charlesbank Equity Fund II v. Blinds to Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004). "The costs of complying with challenged regulations have been recognized as irreparable given the obstacles faced when suing for monetary damages." *Cal. v. Kennedy*, No. 25-12019-NMG, 2025 WL 2807729, at *6 (D. Mass. Oct. 1, 2025) (citing *Rosario-Urdaz v. Rivera-Hernandez*, 350 F.3d 219, 222 (1st Cir. 2003)).

Plaintiffs demonstrate irreparable harm. AHA members alone estimate $400 million in compliance costs, the downstream effect causing them to cut back services and suspend partnerships with drug distributors. Mot. at 16-19; Reply at 11-12; Golder Suppl. Decl. ¶¶ 2-4; Austin Decl. ¶¶ 10-13; Brown Decl. ¶ 18; Fadale Decl. ¶ 18. These claims are not unsubstantiated fears of what the future might hold. Nor do Plaintiffs' speculative concerns about delayed receipt and inappropriate denial of rebates from drug manufacturers defeat the meritorious aspects of their irreparable harm claim. Furthermore, because Plaintiffs raise an APA challenge, they cannot recover any damages for the costs incurred from the Rebate Program should it later be invalidated—a claim on which they are likely to succeed. Accordingly, their inability to recoup those costs in this context demonstrates irreparable harm. *Kennedy*, 2025 WL 2807729, at *6.

3. Balance of Equities and Public Interest

Plaintiffs maintain that the balance of equities and public interest weigh in their favor for several reasons, including the public's interest in preserving the reach of the Public Health Service to provide critical medical services, particularly when weighed against the lack of public interest in an agency carrying out a likely unlawful action. Mot. 19-20. Defendants assert that there is strong public interest in implementing the Rebate

Program to address the de-duplication problem and assess the benefits of a rebate model. Opp'n at 22.

The balance of equities and public interest weigh in Plaintiffs' favor. Most importantly, a preliminary injunction would preserve the status quo and preserve the reach of 340B entities to continue serving the public's significant interest in receiving critical medical services. *See Starbucks Corp. v. McKinney*, 602 U.S. 339, 344 (2024); *Rio Grande Cmty. Health Ctr., Inc. v. Rullan*, 397 F.3d 56 (1st Cir. 2005). Moreover, considering that Plaintiffs are likely to succeed on the merits of their APA claims, Defendants' arguments concerning equities and public interest in the Rebate Program are necessarily diminished. To be clear, Defendants' authority to administer a rebate model program is not in question, only the quality of the Rebate Program's current rollout effort in light of the APA.

4. Summation

As complicated as certain aspects of this case might seem, it boils down to a simple principle. Defendants cannot fly the plane before they build it. The Agency's failure to abide basic requirements of the APA, Plaintiffs' irreparable injury should the program go into effect, as well as the balance of equities weighing in Plaintiffs favor, all counsel against permitting the Rebate Program to take flight on January 1, 2026.[6] That, of course, is not to say that a rebate model is impermissible. Congress clearly gave Defendants that option. The problem is that the Defendants' failed to follow the APA's basic blueprint in

[6] April 1, 2026, for the application approved for Novartis Pharmaceuticals Corporation. *See* Opp'n at 7.

assembling the Rebate Program. For these reasons, Defendants are preliminarily enjoined from implementing this iteration of the Rebate Program pending further order.

C. SCOPE OF PRELIMINARY RELIEF

1. Preliminary Injunction

Defendants' cite *Trump v. CASA, Inc.*, 606 U.S. 831 (2025), for the proposition that the breadth of this preliminary injunction is limited to the specific identified association members of AHA and MHA or that the remedy should be tailored only to address the irreparable harm shown by specific members of these associations. Opp'n at 23-25. First, *Casa* declined to "resolve[ ] the distinct question whether the [APA] authorizes federal courts to vacate federal agency action." *CASA*, 606 U.S. at 847 n.10. Second, the First Circuit has already rejected Defendants argument that the remedy here must be limited to the "members whom the organizations identified in seeking associational standing." *Doe v. Trump*, 157 F.4th 36, 80 (1st Cir. 2025).

The APA authorizes federal courts to "hold unlawful and set aside agency action," 5 U.S.C. § 706(2), including by "issu[ing] all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings," *id.* § 705. Defendants fundamentally misunderstand the nature of this 'set aside' authority, which "'empower[s] the judiciary to act directly against the challenged agency action.'" *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 838 (2024) (KAVANAUGH, J., concurring) (quoting J. Mitchell, *The Writ-of-Erasure Fallacy*, 104 VA. L. REV. 933, 1012 (2018)). Moreover, courts have long understood the APA to authorize vacatur and the Supreme Court has yet

to dictate otherwise. *Id.* at 839; s*ee also Assoc. of Am. Univ. v. Dept. of Defense*, No. 25-11740-BEM, 2025 WL 2899765, at *29 (D. Mass. Oct. 10, 2025) (citing cases); *Doe v. Trump*, 796 F. Supp. 3d 599, 603 (N.D. Cal. 2025) (citing cases). As a result, the preliminary injunction in this case—based in part on a finding that the government's application approvals likely violated the APA—need not be limited to Plaintiffs. Instead, the Court has authority to preliminarily set aside those agency actions comprising the Rebate Program. *See CASA*, 606 U.S. at 873 (KAVANAUGH, J., concurring) (noting that even after *CASA*, district courts may "grant or deny the functional equivalent of a universal injunction—for example, by . . . preliminarily setting aside or declining to set aside an agency rule under the APA"); 5 U.S.C. § 705.[7]

2. Bond Requirement

In this case, a nominal bond is appropriate. Although the APA has no bond requirement, *id.* § 705, "the district courts in this circuit have generally required a bond," *Maine v. U.S. Dept. of Agric.*, 778 F. Supp. 3d 200, 237 (D. Me. 2025). Defendants face no material loss from enjoining the implementation of the Rebate Program, Plaintiffs' lawsuit concerns the public interest, and Plaintiffs are likely to succeed on the merits of their claim. *See Crowley v. Local No. 82, Furniture & Piano Moving*, 679 F.2d 978, 999-1000 (1st Cir. 1982). Accordingly, Plaintiffs must post a bond of $1,000.[8]

[7] Of course, the broad latitude the APA affords courts to fashion relief does not necessarily preclude more limited remedies, including remand for further consideration by the agency consistent with a court order. *See*, *e.g.*, *State Farm*, 463 U.S. at 59.

[8] This District and other district courts within the First Circuit have similarly required a nominal bond in this amount. *See Maine*, 778 F. Supp. 3d at 238; *Nationwide Payment Sols., LLC v. Plunkett*, 697 F. Supp.

CONCLUSION

For the foregoing reasons, Plaintiffs' Motion (ECF No. 3) is GRANTED. Defendants are enjoined from implementing the nine individual applications that comprise the 340B Model Rebate Pilot Program pending further order. Furthermore, within seven days of the date of this order, Plaintiffs are ORDERED to provide security in the amount of $1,000.

SO ORDERED.

/s/ Lance E. Walker
Chief U.S. District Judge

Dated this 29th day of December, 2025.

2d 165, 173 (D. Me. 2010); *Nw. Selecta, Inc. v. Sec'y of the Dep't Agric. of P.R.*, No. 22-1092-RAM, 2022 WL 17985926, at *7 (D.P.R. Dec. 29, 2022). I see no reason to depart from this precedent.