UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, ET AL., Plaintiffs, v. ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, ET AL., Defendants.	Case No. 1:26-cv-00515-LEW

PLAINTIFFS' REPLY TO DEFENDANTS' AND DEFENDANT-INTERVENORS' OPPOSITIONS TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

PRELIMINARY STATEMENT

Last year, this Court urged Defendants to go back to the drawing board and "fortify the pilot rebate program rather than attempting to lower the bar for administrative action." *Am. Hosp. Ass'n v. Kennedy*, 2025 WL 3764086, at *1 (D. Me. Dec. 30, 2025). Despite the benefit of this Court's roadmap, Defendants failed to do the former, so they and Intervenors again resort to the latter. At every turn, their opposition briefs would tear up the "APA's basic blueprint," *Am. Hosp. Ass'n v. Kennedy*, 820 F. Supp. 3d 30, 47 (D. Me. 2025) ("*AHA I*"), replace it with a standard unrecognizable under *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29 (1983), and recast failures of reasoned decisionmaking as mere policy disagreements.

Consider benefits. This Court previously held that costs and benefits are important aspects of the problem under *State Farm* and that an "agency must identify benefits that 'bear a rational relationship to the . . . costs imposed.'" *AHA I*, 820 F. Supp. 3d at 44 (quoting *Mexican Gulf Fishing Co. v. U.S. Dep't of Com.*, 60 F.4th 956, 973 (5th Cir. 2023)). Yet Defendants say almost nothing about the Rebate Program's supposed benefits. They neither quantify those benefits nor explain how the Program would *incrementally* address the problem it purports to solve—a problem Defendants and Intervenors appear to disagree about. Without a reasoned evaluation of benefits,

the Court cannot assess whether they bear a rational relationship to costs. This threadbare approach to benefits would not just lower the bar for administrative action. It would eliminate it altogether.

Consider administrative costs. Contrary to this Court's prior holding, Intervenors argue that the APA permits an unquantified, incomplete, and inadequately explained assessment of costs. ECF Doc. 80 at 10–11; ECF Doc. 78 at 10. Just as bad, Defendants spend two pages cutting-and-pasting the Notice's discussion of administrative costs, then assert in a single sentence that the agency discharged its obligations by "consider[ing]" them. ECF Doc. 79 at 11–14. But "stating that a factor was considered . . . is not a substitute for considering it." *Nat'l Treasury Emps. Union v. Horner*, 854 F.2d 490, 499 (D.C. Cir. 1988) (citation omitted). And in any event, *State Farm* requires more than mere "consideration." An agency cannot "'simply summarize[]' the party's argument 'in broad strokes' and then 'announce' that it is persuaded." *Affirmed Energy, LLC v. FERC*, 166 F.4th 1070, 1083 (D.C. Cir. 2026) (citation omitted). It must go beyond dueling summaries to "critically review" the submissions and explain why it finds one persuasive. *Id*. That explanation cannot "run[] counter to" the evidence, *State Farm*, 463 U.S. at 43, including, here, the extensive and detailed evidence from covered entities (who know their own operations best) that the Program will require far more than five hours of labor per week. And an agency's ultimate decision must be reasonable, which it cannot be if the agency "fail[s] adequately to quantify certain costs." *Presidents' All. on Higher Educ. & Immigr. v. DHS*, 2026 WL 2690098, at *15 (D. Mass. Sept. 14, 2026) (quoting *Bus. Roundtable v. SEC*, 647 F.3d 1144, 1148–49 (D.C. Cir. 2011)).

Consider reliance interests. Defendants and Intervenors entirely retreat from the Notice's principal explanation for dismissing covered entities' reliance interests: that statutory discretion rendered any reliance unreasonable as a "matter of law." Compl. ¶ 273. They instead repeat the Notice's conclusory assertion that the Program's benefits outweigh those interests. But where, as

here, an existing policy has engendered decades of "serious reliance interests," the law imposes a more demanding standard. As the First Circuit recognized, Defendants must provide a "more detailed justification." *Am. Hosp. Ass'n v. Kennedy*, 164 F.4th 28, 33 (1st Cir. 2026) ("*AHA II*") (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)).

The list goes on—other types of costs, less burdensome alternatives, other important aspects of the problem, and more. But the central point is straightforward. Defendants and Intervenors cannot defeat Plaintiffs' showing of likely success on the merits by simply regurgitating conclusory statements from the Notice. They must answer Plaintiffs' arguments *why* the Notice's treatment of the evidence and ultimate decision fail under *State Farm*. They do not come close to doing so. Plaintiffs are therefore likely to succeed under the APA's ordinary standard of review, much less the more demanding standard that applies when an agency reaches the same decision after remand, ECF Doc. 2 ("Mot.") at 5 (citing *Greyhound Corp. v. ICC*, 668 F.2d 1354, 1358 (D.C. Cir. 1981))—a standard Defendants and Intervenors conspicuously *do not* dispute.

Defendants and Intervenors likewise fail to rebut Plaintiffs' showing that "the remaining factors strongly favor" a preliminary injunction. *Nat'l Tr. for Hist. Pres. v. Buttigieg*, 2023 WL 4847260, at *4 (D. Me. July 28, 2023). They introduce no evidence disproving that last year's irreparable injury still exists today: hundreds of millions of dollars in conceded costs that will have "the downstream effect [of] causing [340B hospitals] to cut back services." *AHA I*, 820 F. Supp. 3d at 46. And the public interest and balance of equities still tilt heavily toward preserving the status quo so "340B entities . . . continue serving the public's significant interest in receiving critical medical services." *Id*. The Rebate Program should be enjoined before January 1, 2027.

ARGUMENT

I. Plaintiffs Have Established a Likelihood of Success on the Merits

Defendants do not—and cannot—dispute that the Rebate Program is subject to the APA's "reasoned decisionmaking" requirement under § 706 and *State Farm*. *See, e.g.*, *Butte Cnty. v. Hogen*, 613 F.3d 190, 195 (D.C. Cir. 2010); *AHA I*, 820 F. Supp. 3d at 40. Defendants fail to satisfy that standard for every Count in Plaintiffs' Complaint.[1]

Count I (Relevant Factors). Defendants and Intervenors do not dispute that 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 v. Holder*, 565 U.S. 42, 64 (2011)). Nor do they dispute that a rebate mechanism is *not* 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). Instead, they attack an argument Plaintiffs do not make.

All three argue that the 340B statute provides discretion to approve a payment mechanism and that a committee report cannot "divest[] HHS of this statutory discretion." ECF Doc. 79 at 8; *see* ECF Doc. 80 at 9; ECF Doc. 78 at 7. But Plaintiffs challenge the *exercise* of discretion, not its existence. The D.C. Circuit recognized HHS's discretion. *See Novartis Pharm. Corp. v. Kennedy*, 182 F.4th 1027, 1030 (D.C. Cir. 2026). But it also made clear that the committee report supplies the relevant factor governing that choice: the "standpoint" standard. *Id.*

Plaintiffs agree with Defendants that committee reports are "not positive law." ECF Doc. 79 at 8. But that is beside the point. Foundational precedent holds that committee reports *can*

[1] Just like last year, the "paucity of the administrative record" is a "significant flaw with Defendants' institution of the Rebate Program." *AHA I*, 820 F. Supp. 3d at 40. The PAR is more than 30,000 pages long (including nearly 9,000 pages of comments on last year's program), but not a single page contains "internal deliberative materials," *Dep't of Com. v. New York,* 588 U.S. 752, 782 (2019), nor anything else that illuminates HRSA's reasoning. Indeed, Defendants' opposition brief spends 15 pages defending the merits but cites only **three** of the thousands of documents in the PAR: (1) the Notice, (2) the June ICR, and (3) the August 4, 2026, OMB Supporting Statement, which is cited only because the Notice printed an incorrect burden calculation. The rest of the PAR serves a decorative role for Defendants, but a decisive one for Plaintiffs given the many important problems identified in the comments, which HRSA never reasonably addressed, and the powerful evidence that runs counter to HRSA's conclusions.

supply the factors relevant to an agency's exercise of discretion. After all, *State Farm* itself quoted two congressional reports when identifying the relevant factors. *See* 463 U.S. at 55. Immediately before doing so, the Court directed the agency on remand to "bear in mind that Congress intended safety to be the preeminent factor under the Motor Vehicle Safety Act." *Id.*; *cf Judulang*, 565 U.S. at 55 (holding that "the purposes of the immigration laws or the appropriate operation of the immigration system" serve as "non-arbitrary, relevant factors" under *State Farm* (cleaned up)).[2]

Neither Defendants nor Intervenors claim that HHS's discretion is unfettered. Yet they identify no source (other than the committee report) for the factors governing that discretion—much less a *congressional* source for the agency's invented balancing test. *See* Compl. ¶¶ 220–221; 91 Fed. Reg. 48,883, 48,887–88 (Aug. 3, 2026). In fact, Defendants concede "the committee report flagged certain factors that it expected HHS to consider" but insist that the "standpoint standard" need not "control over all others." ECF Doc. 79 at 9. But they do not explain how Congress's expectation that HHS will select the "*most* effective and *most* efficient" mechanism permits it to favor "other" considerations that make a mechanism *less* effective or efficient for covered entities. That is why Defendants applied and endorsed the "standpoint standard" in the past, and why they were required to apply it here. *See* Compl. ¶ 219; *see also Johnson & Johnson Health Care Sys. Inc. v. Kennedy*, 2025 WL 1783901, at *10 (D.D.C. June 27, 2025) ("[A]s the statute's House Report expected, HRSA has exercised its authority . . . to determine 'the most

[2] Neither the Government nor PhRMA addresses *Grinspoon v. DEA*, 828 F.2d 881, 893–94 (1st Cir. 1987), or *Melone v. Coit*, 100 F.4th 21, 33 (1st Cir. 2024), which both relied on committee reports to identify limits on agency discretion. Drug Company-Intervenors address these cases only briefly, invoking the principle that legislative history must have a "statutory reference point." ECF Doc. 80 at 9 & n.3 (quoting *Shannon v. United States*, 512 U.S. 573, 584 (1994)). The "standpoint standard" has one. In the words of *Shannon*, 512 U.S. at 583, that standard is "anchored in" Congress's authorization for HHS to "provide" for rebates or discounts. *See Novartis Pharms. Corp.*, 182 F.4th at 1035 (linking the "key committee report['s]" standpoint standard to the statutory "phrase 'as provided by the Secretary'").

effective and most efficient' mechanisms for implementing 340B pricing." (citation omitted)).[3]

Separately, Intervenors say nothing about the 340B statute's *overall* purpose; Defendants say little more. None disputes that Congress sought to "enable [covered] entities 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. Nor do they dispute that courts and Defendants themselves have recognized that purpose—or that this overall purpose comes from the same committee report they now attack. But rather than explain how forcing covered entities to spend (at least) $500 million on costs instead of patient services is moored to that purpose, Defendants repeat the Notice's unconvincing *ipse dixit* that the Rebate Program does not depart from it. ECF Doc. 79 at 9, 17. That conclusory response does not satisfy *Judulang*.

Count II (Costs). Defendants and Intervenors do not dispute that HRSA's *only* calculation of the Rebate Program's costs is $537 million per year just for covered entities to submit claims data. Mot. at 7. This number is derived from HRSA's determination that claims submission will only take 5 hours per week. *Id*. Plaintiffs alleged that HRSA never explained the basis for this estimate or anything about the methodology HRSA used. *Id*.; *see* Compl. ¶¶ 187–94. Yet neither Defendants nor Intervenors explain where this critical (albeit incomplete) cost figure comes from. Defendants did not include a single new document in the PAR detailing HRSA's methodology—no internal memoranda, no spreadsheet listing the hour figures it used to derive its average, no emails from agency economists, no back-of-the-envelope calculation. Nothing.

At most, Defendants merely repeat what they said in the Notice. They reiterate that this figure was based on a "task-based methodology that considers the discrete activities required to

[3] For this reason, Defendants (ECF Doc. 79 at 19) and Intervenors (ECF Doc. 78 at 2; ECF Doc. 80 at 2) are wrong that Plaintiffs oppose all rebate mechanisms. When a rebate is most effective and efficient for a certain type of covered entity, as for AIDS Drug Assistance Programs, HRSA approval does not violate *State Farm*'s "relevant factor" test.

complete a reporting cycle." ECF Doc. 79 at 11. But that is not a remotely reasonable explanation. Defendants provide no information for how costs were actually calculated under this jargony "task-based methodology" or what data was inputted into this methodology to arrive at the agency's five-hour figure. Defendants elsewhere argue that "that five hours per week represented a reasonable average burden across a range of [covered] entities." *Id.* at 12 (footnote omitted). But, again, that statement reveals nothing of substance. It does not explain the source of that labor-hour estimate or what "range of entities" HRSA included. This is particularly problematic because HRSA recognized that "actual burden may vary among respondents" and "[n]umerous commenters submitted organization-specific burden estimates that substantially exceeded HRSA's estimate." Compl. ¶ 190 (quotation marks omitted). Without any details about how they calculated costs, Defendants' arguments are again nothing more than a "naked claim that we should simply take their word for it." *AHA I*, 820 F. Supp. 3d at 45; *see Nat'l Treasury Emps.*, 854 F.2d at 499 (rejecting a "bald and unsubstantiated claim" on costs); *Presidents' All.*, 2026 WL 2690098, at *15 (similar).

Defendants and Intervenors avoid addressing what is now obvious: HRSA "utilized no principled method by which to meaningfully compare costs and benefits." *Id*. HRSA arrived at its five-hour estimate by taking last year's (unsupported) two-hour estimate and multiplying it by 2.5, which is the increase in the Program's proposed scope from 2025 to 2026. *See* ECF Doc. 78 at 9–10; ECF Doc. 79 at 11; ECF Doc. 80 at 11. But HRSA did not explain its two-hour calculation last year—a fact this Court found "[f]atal" to Defendants' arguments about costs. *AHA I*, 820 F. Supp. 3d at 44. And this year, HRSA not only fails to justify that original input, but also offers no explanation as to why its previous two-hour estimate scales linearly to the increased scope of the new Program. HRSA's assessment of costs, which is "based on an unexplained methodology," is arbitrary and capricious. *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir.

2012) (citation omitted).

The absence of any explanation for HRSA's (partial) cost analysis is all the more indefensible given the overwhelming record evidence that five hours per week dramatically understates the time and cost required to submit claims data. Defendants insist that their estimate "reflect[s] overall operational impacts rather than incremental time required to complete individual reporting responses." ECF Doc. 79 at 11. But commenters provided irrefutable evidence that the additional data submission burden alone was many multiples of what HRSA estimated. *See, e.g.*, Compl. ¶¶ 73–79, 144–48; Mot. at 7; Martson Decl. ¶¶ 19, 21; Denton Decl. ¶ 26; Nahoopii Decl. ¶¶ 9, 13–15. Defendants do not dispute the caselaw holding that Plaintiffs know their own operations best. *See* Mot. at 10; Compl. ¶ 21. Yet HRSA "simply ignore[d] contrary evidence" and "engage[d] with only that evidence which supports [its] conclusion." *Petrone v. Long Term Disability Income Plan*, 935 F. Supp. 2d 278, 293 (D. Mass. 2013) (citations omitted).

Like last year, the Court could stop here and find a likely APA violation. But Defendants further concede that they never quantified or included **other types of costs**. Neither they nor Intervenors refute Plaintiffs' arguments that the Notice unreasonably dismissed them.

- **Lost Cost-of-Goods-Sold, Prompt-Pay, and Other Discounts**: HRSA never addressed certain discounts that would be lost entirely under its Program. *See* Compl. ¶¶ 16(c), 104–05, 170, 244(a); Marston Decl. ¶ 31. The Notice referred once to cost-of-goods-sold discounts, but never returned to them when conducting its cost analysis. *Id*. ¶ 16(c). No opposition brief mentions these lost discounts or defends their exclusion from HRSA's analysis.
- **Startup Costs**: Defendants and Intervenors rehash the Notice's discussion of startup costs. *See* ECF Doc. 79 at 12–13; ECF Doc. 78 at 10; ECF Doc. 80 at 12. They do not, however, engage with the fact that HRSA recognized that these costs would exist but illogically excluded them

from the cost-benefit analysis because they are "transitional." Compl. ¶¶ 16(b), 157, 236(b).

- **Vendor and Training Costs**: Defendants and Intervenors do not dispute that the Rebate Program will impose new vendor and training costs (far beyond what the drug companies will pay for). ECF Doc. 79 at 13; ECF Doc. 78 at 11; ECF Doc. 80 at 12–13. But they never quantify these costs. Nor do they defend the logic of excluding these *incremental* costs simply because the 340B Program has always entailed some operational costs. *See* Compl. ¶¶ 16(a), 236(c).
- **Reconciliation Costs**: The record shows that reconciliation—not claims submission—will be the most expensive component of the Rebate Program. Compl. ¶¶ 80–81 & n.2, 133–34, 149–54; *see* Nahoopii Decl. ¶¶ 18, 25–26; Denton Decl. ¶ 28; Marston Decl. ¶ 23; Fadale Decl. ¶ 25; Bertilrud Decl. ¶ 24. Defendants never dispute this and expressly acknowledge that "the upfront discount model . . . reduces the need for post-purchase reconciliation." ECF Doc. 79 at 12. HRSA tried to brush aside this new category of costs by pointing to unnamed "IT systems" to handle these new reconciliation burdens that exist in the "marketplace," 91 Fed. Reg. at 48,893—as if the "marketplace" will offer these services for free. Defendants and Intervenors also do not address the overwhelming evidence (submitted by those who actually run 340B programs) that some covered entities will need to perform manual reconciliation. *See* Compl. ¶ 80; Nahoopii Decl. ¶ 17; Denton Decl. ¶ 28; Bertilrud Decl. ¶ 24. Ultimately, neither Defendants nor Intervenors explain why HRSA's cost analysis can exclude *entirely* what undisputedly will be the most expensive part of the Program.
- **"Float" Costs**. Defendants' and Intervenors' defense of the Notice's treatment of "float" costs fails for three reasons. *First*, they do not grapple with the Notice's fundamental legal deficiency: HRSA *uncritically* adopted drug company assertions about "float" costs. *See Cboe Futures Exch., LLC v. SEC*, 77 F.4th 971, 979 (D.C. Cir. 2023) ("unquestioning reliance on a

regulated entity's submissions" is arbitrary and capricious (cleaned up)). While HRSA may credit a regulated party's submission, there is no indication that the agency "critically reviewed" the evidence or "performed its own" analysis. *Susquehanna Int'l Grp., LLP v. SEC*, 866 F.3d 442, 447 (D.C. Cir. 2017). HRSA's rote summary of covered entities' concerns about "float" costs does not amount to a critical review of the evidence submitted. *See Affirmed Energy*, 166 F.4th at 1083.[4] *Second*, Defendants and Intervenors are silent about important aspects of "float costs" that the Notice failed to reasonably address. For example, the opposition briefs say *nothing* about the risk of breaching bond covenants. Compl. ¶¶ 101, 103, 158, 209; *see* Marston Decl. ¶ 29; Austin Decl. ¶ 16. That omission is particularly glaring given this Court's prior holding that "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. *Third*, HRSA dismissed float costs based on its assumption that rebates would be paid within 10 days of claim submission. ECF Doc. 79 at 15; ECF Doc. 78 at 12. But HRSA's reliance on that timeline runs contrary to the record evidence, which reflects the reality that (1) many wholesalers require payment in fewer than 10 days[5]; (2) drug

[4] This shortcoming is uncommonly clear in HRSA's treatment of the drug-company funded studies that the agency's conclusion was "based on." 91 Fed. Reg. at 48,894. HRSA has not produced any records suggesting that it weighed the many comments about the studies' limitations, including their unrealistic assumptions about wholesaler payment timeframes and the limited scope of their cost calculations. *See* Compl. ¶¶ 161–65. Unsurprisingly, moreover, Defendants do not defend the embarrassing fact that their Notice relied on an outdated version of the key IQVIA study. *Id.* ¶ 163. The updated version of that study directly refuted Defendants' assertion that wholesalers demand payment in 10 or more days and calculated $53.7 million in annual interest costs for just ten drugs in the Rebate Program—a number that Defendants excluded entirely from their cost-benefit analysis. *Id*. Intervenors pluck stray language from the updated study in an unavailing effort to demonstrate that the two studies are consistent, *see* ECF Doc. 78 at 12; ECF Doc. 80 at 13 n.6, but nowhere address these consequential changes between the two studies.

[5] Defendants fault Plaintiffs for not "identify[ing] the wholesalers in question." ECF Doc. 79 at 15. It is not clear why Plaintiffs bear the burden under the APA to provide that level of detail. Here, the administrative record plainly identified wholesaler repayment terms that are less than 10 days. *See* Compl. ¶¶ 94 & n.3, 243. Even the revised IQVIA study that Defendants ignored, but was cited in the administrative record, credits wholesaler terms requiring payment in less than 10 days. *See* Compl. ¶ 243. And Plaintiff Dallas County Medical Center has since submitted an unrebutted declaration explaining that "certain of our wholesalers require daily payment." Denton Decl. ¶ 21.

inventory can sit for weeks before dispensing; (3) the 10-day clock starts only *after* claim submission, which often takes 30 to 45 days; and (4) repayment delays and denials will inevitably occur, particularly given the recent MFP program track record. *See* Compl. ¶¶ 94–97, 158, 244(c). An agency cannot disregard such contrary facts and data. *Fox*, 556 U.S. at 537. It must engage with "evidence that undercuts its judgment" instead of "minimiz[ing] [it] without adequate explanation." *Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018).

- **Non-economic Costs**. This Court previously held that the "non-monetary costs to 340B entities, including the impact these additional prices might have on their long-term viability," were an "unaddressed 'important aspect of the problem.'" *AHA I*, 820 F. Supp. 3d at 44. This Court also recognized that spending hundreds of millions of dollars on administrative costs will have "the downstream effect [of] causing [hospitals] to cut back services," *id.* at 46, and that HRSA may not show "casual indifference to localized impacts," *id.* at 45 n.5. Defendants now dismiss those inevitable harms to patient care as a "fanciful worst-case scenario." ECF Doc. 79 at 17. But that response flies in the face of abundant record evidence, *see* Compl. ¶¶ 4, 17, 106–115, 210–12, this Court's prior reasoning, and pure common sense.

Having failed to reasonably quantify or evaluate costs, Intervenors ask this Court to apply a more forgiving standard of review than it applied to HRSA's first Rebate Program. *Compare* ECF Doc. 80 at 10–11, *and* ECF Doc. 78 at 10, *with AHA I*, 820 F. Supp. 3d at 44; *id*. at 45 (rejecting Defendants' arguments about costs because they were contradicted by "numerous public comments estimating hundreds of millions of dollars in additional costs to 340B hospitals they might struggle to pay under a rebate model"). Intervenors identify no basis for departing from the Court's holding in favor of a less exacting standard that permits incomplete and unquantified cost calculations, and judges across the country have recently rejected comparably deficient cost

analyses under the familiar *State Farm* standard. *See, e.g.*, *Presidents' All.*, 2026 WL 2690098, at *15; *Chamber of Com. of the U.S.*, 820 F. Supp. 3d 473, 491 (E.D. Tex. 2026).

Defendants insist that they discharged their APA burden solely because they *considered* costs, as evidenced by the passages from the Notice they rotely reproduce in their brief. *See* ECF Doc. 79 at 14. But "awareness [of costs] is not itself an explanation." *Ohio v. EPA*, 603 U.S. 279, 295 (2024). The quoted passages prove only that HRSA named certain types of costs and then arbitrarily dismissed them without the required analysis or rational reasoning. *See Presidents' All.*, 2026 WL 2690098, at *15 (agency decision that "did not even attempt to quantify the actual costs and purported benefits," "much less perform a reasoned balancing," "was egregiously flawed and incomplete").

Count III (Benefits/Rational Relationship to Costs). Defendants failed to reasonably evaluate the Program's purported benefits. The Notice's analysis of benefits merely parrots two drug-industry figures of Medicaid duplicate discounts without examining their reliability, methodology, or self-interested sourcing. *See* Mot. at 14; Compl. ¶¶ 139, 252. Defendants now barely mention those parroted figures, let alone defend them. *See* ECF Doc. 79 at 10. Nor do they respond to Plaintiffs' observation that HRSA possesses its own audit data regarding the frequency of duplicate discounts but ignored that data. Compl. ¶¶ 140–141, 253.

Defendants also do not address the Notice's reliance on estimates of *overall* Medicaid duplicate discounts rather than the *incremental* benefits of this Rebate Program. *Id.* ¶¶ 20(b), (d). Comparing overall duplicate discounts with a Program covering only 18 drugs "mixes apples and oranges," and thus reflects the sort of "[i]llogic and internal inconsistency [that is] 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, 381–82 (5th Cir. 2018); *see Bus. Roundtable,* 647 F.3d at 1148–49 (agency may not

"inconsistently and opportunistically frame[] the costs and benefits").

Defendants also do not confront the fact that the Program cannot remedy Medicaid duplicate discounts. HRSA expressly prohibits manufacturers from denying rebates "based on eligibility or compliance concerns with diversion or Medicaid duplicate discounts." 91 Fed. Reg. at 48,903; *see* Compl. ¶¶ 258–59. Agency action premised on an ineffectual solution is paradigmatic arbitrary and capricious decisionmaking.

So the Notice offers only "vague and conclusory assertions" of benefits. *Chamber of Com. of the U.S.*, 820 F. Supp. 3d at 489. Without more, Defendants cannot satisfy their burden under the APA to "identify benefits that 'bear a rational relationship to the . . . costs imposed.'" *AHA I*, 820 F. Supp. 3d. at 44 (quoting *Mexican Gulf Fishing Co*., 60 F.4th at 973).

Perhaps recognizing this deficiency, Intervenors recharacterize the Program's purpose and benefits. Although the Notice speaks of program-integrity concerns more generally, Intervenors now portray the Program as directed at deduplication under the Medicare Drug Price Negotiation Program (MDPNP). *See* ECF Doc. 80 at 2, 14; ECF Doc. 78 at 13. Drug Company Intervenors concede that the Pilot Program "does not address *Medicaid* duplicate discounts," ECF Doc. 80 at 14, yet they identify no record evidence that HRSA estimated the benefits of preventing 340B-MDPNP duplications. Even if 340B-MDPNP deduplication was one of several goals of the Rebate Program, the record is fatally silent about how much the Rebate Program would save for *that* kind of deduplication or how *those* savings would rationally relate to the Program's costs.

Intervenors cannot now supply benefits that HRSA itself did not calculate, analyze, or balance against costs. Their declarations cannot fill gaps in the Notice or administrative record about the amount of 340B–MDPNP duplicate discounts. *See* ECF Doc. 80 at 14; ECF Doc. 78 at 18. As this Court recognized, "[i]t 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." *AHA I*, 820 F. Supp. 3d at 41 (cleaned up). Intervenors therefore cannot repair the record's "tatty" and "anemic" treatment of benefits with rationales and estimates that HRSA itself never offered. *Id*. at 40–41. Because HRSA "failed to demonstrate that it would obtain meaningful benefits," the Program is "arbitrary and capricious." *Chamber of Com. of the U.S.*, 820 F. Supp. 3d at 491.[6]

Count IV (Alternatives). Defendants and Intervenors leave unanswered several critical defects in the Notice's evaluation of less burdensome alternatives. For example, they do not dispute that Defendants told two circuit courts that there are other ways to prevent duplicate discounts. Compl. ¶ 175. Nor do they explain why HRSA never addressed its *legal* authority to pursue a third-party clearinghouse. *Id*. ¶¶ 176, 267(b). And they do not defend HRSA's reliance on language copied verbatim from PhRMA's comment letter about covered entities' "incentives" to participate in a neutral clearinghouse. That alone proves HRSA did *not* critically examine PhRMA's unsupported speculation about *covered entities*' incentives or bother to ask covered entities if they would participate in a clearinghouse. *See id*. ¶¶ 178–80, 267(b).[7]

At bottom, Defendants and Intervenors fail to answer the problem inherent in HRSA's

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[6] In an apparent effort to besmirch the 340B Program and the safety-net providers that participate in it, Defendants, Intervenors, and their *amici* repeatedly invoke the Program's growth, sometimes accompanied by inflammatory and unsupported allegations of fraud and abuse. Plaintiff AHA and other commenters explained to Defendants that HRSA's own audit data proves there is far less abuse in the 340B program than the drug industry would have the agency believe. *See* Compl. ¶¶ 140, 254. But HRSA never responded to this information—another basic failure in reasoned decisionmaking. *E.g.*, *Affirmed Energy, LLC*, 166 F.4th at 1083 ("An agency's decision is also arbitrary and capricious if it merely rubberstamps a regulated party's analysis."); *Fred Meyer Stores, Inc. v. NLRB*, 865 F.3d 630, 638 (D.C. Cir. 2017) (an agency that fails to "grapple with contrary evidence . . . disregard[s] entirely the need for reasoned decisionmaking"). In any event, *lawful* growth in a congressional program is not a "problem" for an agency to solve, especially when such growth is entirely consistent with the program's purpose of allowing covered entities to provide more comprehensive healthcare services. Ultimately, if there is a concern about 340B program growth, it is for Congress—not HHS—to address. *See Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022) ("[I]f the statute[] . . . is working in unintended ways, HHS can ask Congress to change the law. Of course, if HHS went to Congress, the agency would presumably have to confront the other side of the policy story here: 340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support.").

[7] Even apart from incentives, Defendants recently finalized a rule that would make a similar clearinghouse mandatory. *Medicare and Medicaid Programs; CY 2027 Payment Policies Under the Physician Fee Schedule*, 91 Fed. Reg. 70,992, 71,312 (Nov. 9, 2026). Commenters suggested a clearinghouse when discussing less burdensome alternatives. *See* Compl. ¶¶ 176–78, 267(b).

consideration of alternatives. They do not dispute that HRSA rejected every non-rebate alternative because preserving upfront discounts "would not inform whether rebates are an efficient means of effectuating the 340B ceiling price." 91 Fed. Reg. at 48,890. Intervenors nevertheless insist that it is "not circular" to "use a rebate mechanism to evaluate a statutorily authorized rebate approach." ECF Doc. 80 at 17; *see* ECF Doc. 78 at 17. But the question under the APA is not whether HRSA must impose a rebate mechanism to test a rebate mechanism. It is whether the Rebate Program, with its attendant costs and burdens, is a reasonable way to achieve HRSA's purported program-integrity goals *compared to the proposed alternatives*. An agency that defines its objective as the chosen action and then rejects every alternative for failing to be that action engages in "circular reasoning"—a "hallmark[] of arbitrary and capricious decision-making." *Am. Pub. Health Ass'n v. NIH*, 145 F.4th 39, 54 (1st Cir. 2025).

Count V (Reliance Interests). Defendants and Intervenors jettison the Notice's principal rationale for rejecting covered entities' reliance interests: that "reliance on an upfront discount model" was unreasonable "as a matter of law" because the statute permits Defendants to approve rebates. 91 Fed. Reg. at 48,888–89. They instead try to defend the Notice's assertion that reliance interests do not "outweigh the significant benefits of proceeding." *Id*. at 48,889; *see* ECF Doc. 79 at 18; ECF Doc. 78 at 15; ECF Doc. 80 at 15.[8] These "conclusory statements do not suffice." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 224 (2016).

"[S]ummary discussion may suffice in other circumstances, but here—in particular because of decades of industry reliance on [HHS's] prior policy—[HHS's] explanation fell short of the

[8] Defendants insist that this is an "alternative" basis for rejecting covered entities' reliance interests. ECF Doc. 79 at 18. But a fair reading of the Notice is much "harder to parse" because the agency's unlawful belief that reliance was *always* unreasonable was "key" to HRSA's decision. *Zzyym v. Pompeo*, 958 F.3d 1014, 1034 (10th Cir. 2020). That was not "some minor misstatement of law or fact that can be passed over as an unfortunate lapse." *Consol. Edison Co. of New York, Inc. v. FERC*, 823 F.2d 630, 641 (D.C. Cir. 1987). HRSA's incorrect view of the law "reflect[ed] [the agency's] pervasive frame of mind . . . about a crucial problem," making Plaintiffs exceedingly likely to succeed on Count V. *Id.* at 641–42.

agency's duty to explain why it deemed it necessary to overrule its previous position." *Id*. at 222; *see also Am. Pub. Health Ass'n*, 145 F.4th at 54. Defendants and Intervenors do not dispute that this Court and the First Circuit found Plaintiffs' reliance interests to be "significant." *AHA I*, 820 F. Supp. 3d at 43; *AHA II*, 164 F.4th at 32. Yet neither the Notice nor the opposition briefs offer a specific, non-conclusory explanation for *why* the Rebate Program's purported benefits outweigh those interests. Nor do they grapple with the specific "facts and circumstances engendered by [the] prior policy," which this Court rightly recognized the agency could not ignore. *AHA I*, 820 F. Supp. 3d at 42. Those circumstances include covered entities' 30-plus years of decisions about operations, staffing, and spending on patient care, all of which were made in reliance on HRSA's decades-long public endorsement of an upfront discount mechanism. The Notice's cursory balancing fails ordinary arbitrary-and-capricious review, much less the "more detailed justification" the First Circuit held is required here. *AHA II*, 164 F.4th at 33 (quoting *Fox*, 556 U.S. at 515); *see also Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 106 (2015).

Count VI (Other Important Aspects of the Problem). Plaintiffs allege that HRSA failed to consider important aspects of the problem, including (1) that starting the Rebate Program in 2027 is especially problematic given the financial headwinds facing 340B hospitals, particularly in light of the One Big Beautiful Bill Act ("OBBBA"); and (2) several documented failures of the drug-company-selected vendor platforms on which the entire Pilot depends. Compl. ¶¶ 99, 114, 132, 186(a), 186(c), 283–84. Neither Defendants nor Drug Company-Intervenors meaningfully address these problems in their briefs. Only PhRMA does, but its answers lack merit.

PhRMA contends that HRSA did not have to consider the effects of the OBBBA because that law "does not even mention the 340B Program." ECF Doc. 78 at 15. But that misses the point. Commenters pointed to the OBBBA only to underscore the problem with starting a so-called

"pilot" program under devastating financial conditions. The timing of a new federal program is indisputably an important aspect of the problem. HRSA ignored it.

PhRMA next asserts that HRSA addressed concerns about the Beacon platform "through the technical requirements for manufacturer rebate plans." *Id.* at 16. But PhRMA identifies no language in the Notice or its manufacturer application approvals that addresses the problems commenters raised about Beacon or explains how the "technical requirements" fix those. *See* Compl. ¶¶ 132, 186(c), 197, 284(a). In reality, Defendants were silent about Beacon's many problems in the Notice, the application approvals, and now their opposition brief.[9]

Plaintiffs understand the Court's reluctance to wade into topics that might "venture into the territory of asking for a policy judgment against the Agency." *AHA I*, 820 F. Supp. 3d at 45. But no policy judgment is required here because Defendants *completely* ignored these important aspects of the problem, rather than making any reasoned decision about how to resolve them (or, at the very least, without offering a reasoned explanation describing how it resolved them). HRSA's *complete* silence about the (1) timing and financial environment when its so-called "pilot" will begin, and (2) the IT platform at the heart of the Program, violates *State Farm* twice over.

Count VII (Predetermined Result). Defendants and Intervenors barely address Plaintiffs' claim that HRSA was committed to a predetermined result. Importantly, they do not confront the

[9] For example, commenters warned HRSA that Beacon could not handle the volume of claims generated by the Rebate Program. Compl. ¶ 132. HRSA never addressed that serious concern, and PhRMA does not explain how a "technical requirement[]" could resolve such a fundamental problem. ECF Doc. 78 at 16. Likewise, commenters raised concerns about Beacon's Terms of Use, including provisions stating that those Terms can be modified at any time. *See* Compl. ¶ 186(c); ECF Doc. 73 at 11–12. HRSA said nothing about this. And Beacon's defense in the Vandervelde Declaration only underscores the problem. He states that covered entities that do not want to accept any revised terms can just "stop using the Beacon Rebate Model." ECF Doc. 80-1 at ¶ 11. But because the Rebate Program requires covered entities to use Beacon, that amounts to saying they must accept whatever terms Beacon imposes or forgo their statutory discounts. This is exactly what commenters feared, but Defendants did not confront Beacon's shocking position then—and neither Defendants nor Intervenors confront it now. *E.g.*, HRSA-2026-0001-1846 at 49 (comment letter of Plaintiff AHA) (describing Beacon's "one-sided, nonnegotiable contract that covered entities would not have otherwise signed if their hands weren't tied," including the provision that "permitted Beacon to unilaterally change contract terms at any point in time").

compelling evidence that HRSA's RFI was merely a "*pro forma* public opportunity to comment," *Davis v. Mineta*, 302 F.3d 1104, 1113 (10th Cir. 2002), and that Defendants were unwilling 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 sub nom. Dep't of Com.*, 588 U.S. at 785. This includes evidence that: (1) the second Rebate Program did not meaningfully differ from the first, and reflexively recycled its cost calculation before ever receiving comments; (2) HRSA uncritically accepted the drug companies' positions on *every* disputed issue; (3) Defendants (undisputedly) held closed-door meetings with drug companies to craft the Program; and (4) HRSA declined further opportunity to comment on the new program's actual details so that it could meet an artificial January 1, 2027 start date. *See* Compl. ¶¶ 14, 67–68, 194, 291–94.

Instead, Defendants and Drug Company-Intervenors insist that there is no "open-mindedness" test under the APA—perhaps tacitly conceding that HRSA's mind was, in fact, closed. ECF Doc. 79 at 19; ECF Doc. 80 at 17. Either way, they again misstate Plaintiffs' claim. Although an agency may *enter* a comment period with policy preferences, it may not disregard important problems identified in those comments to reach a predetermined result contrary to the weight and logic of the evidence. *E.g., Advocs. for Highway & Auto Safety v. Fed. Highway Admin.*, 28 F.3d 1288, 1291–92 (D.C. Cir. 1994) (relevant inquiry is whether the agency "displayed an open mind when considering the comments received *in response to*" its request for public input); *see Davis*, 302 F.3d at 1112–13; *Kingdom v. Trump*, 2026 WL 1746251, at *11–12 (D.D.C. June 17, 2026).

II. Plaintiffs Have Satisfied the Remaining Preliminary Injunction Factors

Irreparable Harm. Just like last year, Defendants' new Rebate Program forces Plaintiffs to incur hundreds of millions of dollars in unrecoverable compliance and float costs. The Notice concedes more than $500 million in data submission costs alone. 91 Fed. Reg. at 48,893. And in

multiple declarations—which the Government does not rebut with any of its own—Plaintiffs detail the devastating financial consequences the Program will inflict if allowed to go into effect. Marston Decl. ¶¶ 18, 20, 26, 31; Bertilrud Decl. ¶¶ 15, 27–28; Denton Decl. ¶¶ 19–20, 31; Fadale Decl. ¶¶ 18, 22; Kane-Lewis Decl. ¶¶ 17, 23; Nahoopii Decl. ¶ 22; Golder Decl. ¶¶ 39, 48, 52; *see also New York v. Kennedy*, 155 F.4th 67, 71, 77 (1st Cir. 2025) (crediting substantial harm demonstrated by "dozens of declarations detailing the harms," which were "uncontroverted facts"). This Court has recognized these harms as irreparable. *AHA I*, 820 F. Supp. 3d at 46. It should do so again.

Defendants and Intervenors do not dispute this Court's prior holding. Instead, Defendants curiously point to covered entities' total assets. *See* ECF Doc. 79 at 24. But 340B hospitals cannot be expected to sell their land, buildings, medical equipment, or other assets just so they can participate in a program Congress enacted for *their* benefit. What's more, Defendants cite these assets to argue that Plaintiffs "already have the practical and financial resources to comply with the rebate program." ECF Doc. 79 at 23. But cold, sterile numbers listed on audit reports and tax forms cannot overcome the contextual information provided in Plaintiffs' unrebutted declarations or the extensive record evidence from AHA's members and other covered entities that they cannot absorb the financial consequences of the Rebate Program. *E.g.*, Compl. ¶¶ 4, 112, 113(a), 213, 225 & nn. 15–16. In any event, a "plaintiff need not demonstrate that the denial of injunctive relief will be fatal to its business." *Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 102 F.3d 12, 18 (1st Cir. 1996); *see Waldron v. George Weston Bakeries, Inc.*, 575 F. Supp. 2d 271, 273 (D. Me. 2008), *aff'd*, 570 F.3d 5 (1st Cir. 2009). As this Court recognized, it is more than enough that Plaintiffs have demonstrated substantiated and unrecoverable financial losses, and "their inability to recoup those costs . . . demonstrates irreparable harm. *AHA I*, 820 F. Supp. 3d at 46.[10]

[10] The Program also will irreparably harm Plaintiffs' patient care mission. As the sworn declarations prove, if the Program goes into effect, covered entities will be forced to cut critical patient service lines or shut down entirely,

Balance of Equities/Public Interest. As the First Circuit and this Court held, a preliminary injunction here "simply preserves the status quo that has existed for more than three decades." *AHA II*, 164 F.4th at 37; *see AHA I*, 820 F. Supp. 3d at 46; *see Rio Grande Cmty. Health Ctr., Inc. v. Rullan*, 397 F.3d 56, 76–77 (1st Cir. 2005). By contrast, the effect of an injunction on Defendants would be minimal: they have "not demonstrated that [they] would expend any unrecoverable funds . . . , nor [have they] demonstrated that a delay in the roll-out of the Rebate Program would cause [them] to suffer any other irreparable injury." *AHA II*, 164 F.4th at 37.[11] And the drug companies "have alternative methods to address the . . . described duplication issue," *id.*, as shown by HRSA's representations to the First and D.C. Circuits and the fact that other drug companies declined participation in the Rebate Program, *see* Compl. ¶¶ 175, 179 n.10. Plaintiffs' APA claims are likely to succeed, and there is "no public interest in the perpetuation of unlawful agency action." *Somerville Pub. Schs. v. McMahon*, 139 F.4th 63, 76 (1st Cir. 2025) (citation omitted).

CONCLUSION

Last year, this Court gave Defendants a ready-made blueprint for how to ensure that any revised Rebate Program could satisfy the APA. Defendants did not heed the Court's instructions. HRSA made somewhat "more of an effort" this year, but just like its first version, "the lack of specifics and evidence" in the Notice dooms its second Rebate Program. *Chamber of Com. of the U.S.*, 820 F. Supp. 3d at 490–91. The Court should once again preliminarily enjoin the Program and any drug company application approvals.

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denying care to the most vulnerable patients in the country. *E.g.*, Denton Decl. ¶¶ 8, 33; Marston Decl. ¶¶ 16, 29; Austin Decl. ¶ 21; Golder Decl. ¶ 48. This "suspension of [medical care] and the resulting threats to patients' lives represents a dire risk of a quintessentially irreparable nature." *Massachusetts v. NIH*, 770 F. Supp. 3d 277, 320 (D. Mass. 2025), *aff'd*, 164 F.4th 1 (1st Cir. 2026).

[11] Drug Company-Intervenors claim they will lose money to duplicate discounts without the Pilot Program. For example, AbbVie projects $35.8 million in such losses for 2027. *See* ECF Doc. 80 at 20. This number does not appear in the Notice or AbbVie's comments to the agency. But to put that number in context, in the first nine months of 2026 alone, AbbVie bought back $1.1 billion of its stock—*more than 30 times* its projected 2027 losses without the Pilot Program. *See* AbbVie Inc., Quarterly Report 20 (Form 10-Q) (Nov. 3, 2026).

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