UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, EASTERN MAINE MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER, Plaintiffs, v. ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA, Defendants.	Case No.:

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

REQUEST FOR IMMEDIATE RELIEF

Introduction

1. Almost thirty-five years ago, Congress created a drug pricing program that is essential to safety-net healthcare providers. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992), codified at § 340B, Public Health Service Act, 42 U.S.C. § 256b (1992). Now commonly known as the "340B Program," it allows these providers to purchase certain outpatient medications at reduced cost and use the savings to ensure access to care, improve patient services, and reach America's most vulnerable populations. *See* H.R. Rep. No. 102-384, pt. 2, at 12 (1992). As a unanimous Supreme Court explained a few years ago: "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).

2. Since the 340B Program's enactment, drug companies have been required "to provide discounts to safety-net hospitals at the time of sale." *Am. Hosp. Ass'n v. Kennedy*, 164 F.4th 28, 31 (1st Cir. 2026) ("*AHA II*") (emphasis removed). Requiring drug companies to offer discounted medications at the time of the sale, rather than as a delayed rebate, is known as an "upfront discount." The Health Resources and Services Administration ("HRSA"), a component of the U.S. Department of Health and Human Services ("HHS"), is charged with administering the 340B Program. HRSA has long required this "upfront discount" approach because it both advances the overall purpose of the 340B statute and follows the specific statutory provision governing the mechanism for providing 340B discounts. Many covered entities that participate in the 340B Program operate on razor-thin (or negative) margins and limited cash-on-hand. They cannot afford the costs of paying upfront market prices for drugs without sacrificing the care they provide to patients.

3. For years, drug companies unsuccessfully sought to replace the upfront discount mechanism with what they call a "rebate" mechanism. Such a change would inflict *more than a billion dollars'* worth of annual costs on 340B hospitals. A rebate mechanism, for example, would impose massive administrative costs to submit, track, recover, reconcile, and dispute rebates. In addition, a rebate mechanism would inflict massive "float" costs by forcing 340B hospitals to use their limited cash-on-hand to "pay to the drug manufacturers upfront prices far exceeding the amounts that they actually owe—essentially functioning as an interest-free loan from the hospitals to the manufacturers—and then wait for a rebate." *Id*. at 32.

4. If 340B hospitals are forced to spend all this money on these administrative and "float" costs, the real-world consequences for patients and communities would be devastating: fewer free or discounted drugs for low-income patients; loss of critical medical services in underserved communities; fewer drugs readily available at rural hospitals; fewer staff available to care for patients; and more. Worse still, for some safety-net providers, these costs would prove too much to bear, forcing them to close their doors altogether. Therefore, as the First Circuit explained, "[a]lthough drug manufacturers have previously proposed a switch to a rebate model in which safety-net hospitals would pay higher upfront costs and receive reimbursements later, HHS has historically rejected such proposals as both inferior to Section 340B's current upfront-discount model and disruptive to safety-net hospitals." *Id.* at 31–32.

5. But in August 2025, with no warning to safety-net hospitals, HRSA tried to fundamentally shift the way the 340B Program has operated for thirty-plus years. HRSA announced a "340B Rebate Model Pilot Program" (hereinafter the "Rebate Program" or "Program") that would institute a rebate mechanism for ten of the costliest and most widely used drugs in the Medicare program. Given the crippling costs to caregivers in Maine and nationwide,

Plaintiffs sued on the grounds that the government did not follow basic rules of administrative law. *See* Complaint, *Am. Hosp. Ass'n v. Kennedy*, No. 2:25-cv-600 (D. Me. Dec. 1, 2025), Dkt. No. 1.

6. On December 29, 2025, Chief Judge Walker granted Plaintiffs' request for a preliminary injunction three days before the Program was set to take effect. He held that, under the Administrative Procedure Act ("APA"), Defendants "failed to follow the APA's basic blueprint in assembling the Rebate Program," displayed "casual indifference to localized impacts" of the Rebate Program, failed to consider and reasonably explain the relevant costs, and ignored thirty years of reliance interests. *Am. Hosp. Ass'n v. Kennedy*, 820 F. Supp. 3d 30, 44–45 & n.5, 47 (D. Me. 2025) ("AHA I"). Judge Walker also found that Plaintiffs had demonstrated irreparable harm because, among other things, American Hospital Association ("AHA") "members alone estimate $400 million in compliance costs, the downstream effect causing them to cut back services and suspend partnerships with drug distributors." *Id*. at 46. The First Circuit denied an emergency appeal of Chief Judge Walker's decision, describing the administrative record as "threadbare." *AHA II*, 164 F.4th at 34. Following that decision, the government agreed to vacatur and remand, which this Court granted on February 10, 2026. *See* Order, *Am. Hosp. Ass'n v. Kennedy*, No. 2:25-cv-600 (D. Me. Feb. 10, 2026), Dkt. Nos. 114, 115.

7. A mere week after remand, HRSA issued a new request for information seeking comments "to further evaluate the potential benefits and costs of a rebate model." Request for Information: 340B Rebate Model Pilot Program, 91 Fed. Reg. 7,287, 7,289 (Feb. 17, 2026) ("RFI"). In late February 2026, HRSA published another notice, an information collection request submitted to the Office of Management and Budget ("OMB"), indicating that it anticipated *expanding* its contemplated Rebate Program to 25 of the costliest and most widely used drugs, more than doubling the scope of the first program. *See* Agency Information Collection Activities:

340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW, 91 Fed. Reg. 9,632, 9,632–33 (Feb. 26, 2026) ("February ICR").

8. In response, HRSA received over 2,400 comments, including 1,200 comments from 340B hospitals and other covered entities, and nearly 150 more from associations representing covered entities. These comments described in granular detail the catastrophic impact that a rebate mechanism would have on providers, patients, and communities. Commenters offered specific, facility-level data on the staggering administrative costs of a rebate mechanism, the new full-time employees ("FTEs") hospitals would need to hire, the costs of "floating" hundreds of millions of dollars to drug companies, the valuable discounts hospitals would permanently lose under a rebate mechanism, the non-economic costs on patient care, and many other overlooked costs. They also warned that the timing could hardly be worse: in 2026 and 2027, hospitals will already be absorbing billions of dollars in adverse revenue impacts from the One Big Beautiful Bill Act ("OBBBA"), Pub. L. No. 119-21, and other federal policies, making those years an especially perilous time to impose billions of dollars in new costs.

9. HRSA disregarded these warnings and data. On August 3, 2026, HRSA published a notice announcing its intent to launch its even larger "340B Rebate Model Pilot Program" that could now cover up to 25 drugs. *See* Notice Regarding 340B Rebate Model Pilot Program, 91 Fed. Reg. 48,883 (Aug. 3, 2026) ("Notice"). This new Rebate Program remains a "pilot" in name only. It applies to *every* 340B hospital and covered entity in America, regardless of geographic location, size, services offered, or any other distinguishing factor—totaling more than 15,000 covered entities and more than 49,000 sites by HRSA's own estimate. *Id.* at 48,901. Participation by covered entities is *compulsory* to obtain statutorily owed discounts. By contrast, participation is voluntary for drug companies. *Id.* at 48,900 n.32. The so-called "pilot" also has no clear end date

and, by the words it chose to describe the Program, HRSA seems to presume that it will last for more than one year: "[u]pon conclusion of the *first year* of Pilot operations, HRSA will publish an evaluation by April 30, 2028." *Id.* at 48,901 (emphasis added).

10. On October 1, 2026, HRSA announced the approval of ten drug companies' rebate plans, covering a total of 18 drugs, to begin on January 1, 2027. HRSA, 340B Rebate Model Pilot Program, https://www.hrsa.gov/opa/340b-model-pilot-program ("HRSA Rebate Program Webpage"). By almost doubling the number of drugs covered under the Rebate Program, this so-called "pilot" will increase the costs of the Program as compared to last year and further reduce access to care. In fact, the October approvals *increased* the costs that covered entities will have to bear in ways the Notice itself did not contemplate. For example, the Notice offered repeated assurances that the drug companies' plans will be consistent—that there will be no "manufacturer-specific" requirements or other variations. 91 Fed. Reg. at 48,893. But the approved plans reveal meaningful differences in what HRSA allowed each drug company to require—variations that will further increase covered entities' costs and administrative burdens.

11. HRSA's second Rebate Program violates the "APA's basic blueprint" as starkly as its first. *AHA I*, 820 F. Supp. 3d at 47. Most significantly, it contravenes the blackletter principle that an agency must accurately evaluate the costs and benefits of any regulation. "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, 753 (2015). But even though the First Circuit recognized that a rebate mechanism would impose "significant costs" on covered entities, *AHA II*, 164 F.4th at 34, HRSA has again failed to reasonably consider "the costs and benefits associated with the regulation." *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)).

12. In particular, HRSA "unreasonably understated the costs of the Rule while unreasonably overstat[ing] the benefits," *Chamber of Com. of the U.S. v. FTC*, 820 F. Supp. 3d 473, 491 (E.D. Tex. 2026) (internal quotation marks and citation omitted), and thus failed to "identify benefits that 'bear a rational relationship to the . . . costs imposed.'" *Id.* (quoting *Chamber of Com. of the U.S. v. SEC*, 85 F.4th 760, 777 (5th Cir. 2023)). HRSA "did not even attempt to quantify the actual costs and purported benefits" of the Program, "much less perform a reasoned balancing." *Presidents' All. on Higher Educ. & Immigr. v. U.S. Dep't of Homeland Sec.*, 2026 WL 2690098, at *16 (D. Mass. Sept. 14, 2026). As a result, "the perfunctory and conclusory analysis performed by [HRSA] fails to satisfy even the bare minimum cost-benefit analysis the APA requires." *Id*. "[W]ithout a reasoned cost-benefit analysis," the Rebate Program "is arbitrary and capricious, and therefore violated the APA." *Id*.

13. HRSA's "treatment of the costs" of the Rebate Program, in particular, "was egregiously flawed and incomplete." *Id*. at *15. HRSA estimated that, under the 25-drug Rebate Program, covered entities will spend **$537,222,270 every year** just to submit claims data to drug companies. *See* Notice, 91 Fed. Reg. at 48,893 & n.20; Supporting Statement A, 340B Rebate Model Pilot Program Application, Implementation, and Evaluation Notice, OMB Control No. 0906-NEW (Aug. 4, 2026) ("Supporting Statement"). While staggering, HRSA's half-billion-dollar figure covers only a single administrative burden—submitting claims data. It excludes the massive reconciliation, start-up, information-technology, vendor, training, audit, and dispute-resolution costs that hospitals will need to shoulder—many of which are equally significant, if not greater. The administrative record shows that the full operational costs will, conservatively, exceed

$1 billion a year for 340B hospitals alone. Those hospitals are only approximately 18% of the 15,000 safety-net entities participating in the 340B Program, meaning the actual total cost is many multiples of HRSA's $500 million-plus figure.

14. HRSA's half-billion-dollar calculation rests on the inexplicable assumption that this Rebate Program will require each facility to spend only five hours of pharmacist time per week to comply. But "[f]rankly, the [HRSA] staffing plan[/labor hour] number appears as if pulled from thin air." *Am. Fed'n of Gov't Emps., AFL-CIO v. Trump*, 2026 WL 2677331, at *17 (N.D. Cal. Sept. 11, 2026). Defendants' labor-hour assumption originated back in 2025, *before* receiving a single comment, and they blindly stuck to the same approach this year. The only difference this year is that HRSA took its prior (erroneous and unsupported) labor-hour calculation and multiplied it by 2.5 to capture the 2.5 times as many drugs selected for inclusion in the new Program.

15. To arrive at the same 5-hour-per-week result as before, HRSA ignored the avalanche of comments from covered entities demonstrating that they will have to hire full-time, 40-hour-per-week employees to comply with the new Rebate Program. HRSA never revisited or explained its labor-hour figure after receiving these comments, which showed with specific, hospital-level data that HRSA's 5-hour-per-week estimate is wildly off the mark. Instead, HRSA dismissed those comments in a few conclusory sentences, asserting that it "continues to believe that the estimated burden reasonably reflects the average paperwork burden associated with the information collection," even though it conceded in the next breath that "actual burden may vary." Supporting Statement at 7. All the while, HRSA continued to hide what, if any, methodology or data lies behind its 5-hour-per-week assumption. Accordingly, HRSA failed to address the "important problem[s] the public could and did raise during the comment period," *Ohio v. EPA*, 603 U.S. 279, 298 (2024), and failed to offer the "reasoned response" the law requires. *Id.* at 293;

Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). Put simply, HRSA's approach to labor hours this time around is just as "fatal under the APA" as it was last year. *AHA I*, 820 F. Supp. 3d at 45, 47.

16. HRSA's treatment of several specific categories of additional costs starkly illustrates the deficiencies in Defendants' decision-making and explanation.

a. Many commenters informed HRSA that they would incur significant **vendor and training costs** under a rebate mechanism. HRSA brushed these costs aside by nonsensically arguing "the 340B Program has always entailed some level of compliance and operational cost." 91 Fed. Reg. at 48,894. Just because covered entities have historically incurred certain costs under the "upfront discount" mechanism does not permit HRSA to write off (and refuse to even calculate) the *added* vendor and training costs associated with its new rebate mechanism. Indeed, HRSA recognized this in its initial February 2026 RFI, asking stakeholders to "[e]stimate the *incremental* administrative and operational costs your organization would incur under a 340B Model Rebate Pilot Program." 91 Fed. Reg. at 7,289 (emphasis added). But by excluding vendor and training costs *altogether*, HRSA both underestimated costs and ignored a significant part of the problem.

b. HRSA agreed with covered entities that there would be "legitimate" **start-up costs**. 91 Fed. Reg. at 48,893. But despite abundant record evidence that these costs are substantial (including covered entities' firsthand experience with the first Rebate Program last fall), HRSA neither quantified them nor included them in its cost-benefit analysis. Instead, it dismissed start-up costs *altogether*

because, in its view, they are "transitional" and "inherent to the adoption of a new operational approach." *Id*. But labeling start-up costs as "transitional" does not analyze them, and it certainly is not a reasonable basis for excluding millions of dollars in start-up costs.

c. The administrative record also contains unrebutted evidence of certain customary discounts that 340B hospitals and other covered entities will no longer be able to obtain under a Rebate Program. In particular, covered entities repeatedly explained that they will lose millions of dollars of **prompt-pay and cost of goods sold ("COGS") discounts**. Yet HRSA did not factor these lost discounts into its cost calculations. In fact, the Notice briefly mentions COGS discounts when summarizing covered entities' comments, 91 Fed. Reg. at 48,892, but never returns to them when performing its cost-benefit analysis. They, too, were excluded *altogether*. HRSA's failure to further address and include this undisputed category of "Lost Discount Costs" was arbitrary and capricious. *See Ohio v. EPA*, 603 U.S. at 295 ("[A]wareness is not itself an explanation").

d. HRSA's analysis of the costs associated with fronting hundreds of millions of dollars to drug companies (sometimes referred to in the comments as **"float costs" or "acquisition costs"**) is equally deficient. HRSA included no such costs in its cost-benefit analysis, stating that it "believes that the Pilot is unlikely to result in unstable cash flow for covered entities." 91 Fed. Reg. at 48,894. But its entire support for this conclusion comes from two studies, both of which were self-interestedly funded by the drug industry and substantively

"unpersuasive." *Bus. Roundtable v. SEC*, 647 F.3d 1144, 1150–51 (D.C. Cir. 2011). In fact, HRSA inexplicably relied on a December 2025 study whose authors revised and *increased* their estimates of interest costs in April 2026 because some of the factual underpinnings of their previous work (on which HRSA relied) were incorrect. Moreover, these studies were concededly narrow. They did not address a host of realities that would make having to "float" hundreds of millions of dollars to drug companies even more expensive. These included risks of violating bond covenants, wholesaler escrow requirements, and the practical reality that not all claims would be rebated on time, thereby extending the "float" period beyond any programmatic guardrails. Though raised in many comments, HRSA never addressed these problems when dismissing "float costs" *altogether*.

17. HRSA also irrationally disregarded non-economic costs to patients and communities. The Notice states, without elaboration, that its Program will not "materially impair covered entities' . . . ability to furnish services to patients." 91 Fed. Reg. at 48,899. Nowhere did HRSA acknowledge, as this Court did, the "downstream effect" that requiring covered entities to spend (at least) well over $500 million on claim-submissions will force them to "cut back services." *AHA I*, 820 F. Supp. 3d at 46. Nor did HRSA grapple with the hundreds of covered-entity comments identifying in painstaking detail the specific service lines, community programs, drug price discounts, and operating hours that the Rebate Program will force them to cut. Cost "means more than dollars and cents." *Ky. Coal Ass'n, Inc. v. Tenn. Valley Auth.*, 804 F.3d 799, 802 (6th Cir. 2015). "[A]ny disadvantage could be termed a cost," including "harms that regulation

might do to human health." *Michigan*, 576 U.S. at 752. But HRSA ignored those non-economic costs *altogether*.

18. On the other side of the ledger, HRSA never quantified the benefits from its Rebate Program. It conceded that "there is no federal estimate of the financial extent of duplicate discounts in 340B." 91 Fed. Reg. at 48,887. The only figures it included in the Notice parrot the drug companies' assertions. Thus, HRSA's entire analysis of program benefits was adopted without any critical examination and without acknowledging the wealth of contrary evidence that covered entities submitted demonstrating that the drug companies vastly overstate the number of duplicate discounts that currently exist.

19. Moreover, even HRSA's parroted discussion of duplicate discounts is irrational. For example, HRSA cited assertions by "[m]anufacturer commenters" that duplicate discounts "amounted to as much as $1.5 billion annually." 91 Fed. Reg. at 48,887. But that figure encompasses *all* 340B drugs, not the 25 selected for the proposed Rebate Program, much less the 18 drugs approved to date. HRSA itself stated that the Program would cover "less than 5.5% of total 340B sales" if all 25 drugs were involved. *Id.* at 48,893. A quick back-of-the-napkin calculation (*e.g.*, 5.5% of the $1.5 billion figure equals $82.5 million) suggests the maximum benefits would be limited, but HRSA offered no estimate of the Rebate Program's actual deduplication benefit for this smaller set of drugs. Nor did it explain why it is reasonable to spend billions on administrative costs for what, at best, could amount to a fraction in savings. *See Chamber of Com. of the U.S.*, 820 F. Supp. 3d at 489 ("[T]he FTC's resource-savings argument is limited to a small subset of HSR filers, and the agency again fails to show how that limited benefit reasonably outweighs the significant costs on the thousands of other annual filers.").

20. HRSA's evaluation of the Program's benefits violates the APA many times over:

a. HRSA itself never actually calculated benefits, instead choosing to uncritically adopt data submitted by the drug companies. *E.g.*, *Cboe Futures Exch., LLC v. SEC*, 77 F.4th 971, 979 (D.C. Cir. 2023) (if an agency wants to rely on a regulated party's analysis to support its decision, "it needed to critically review and adopt [the party's] submissions or perform its own comparable analysis" (internal quotation marks omitted)).

b. HRSA never actually identified how much the Rebate Program itself can or will *incrementally* correct the duplicate discount problem it is designed to address. This is a particularly important question since the rules of the Rebate Program affirmatively prevent drug companies from denying rebates even if they suspect a duplicate discount. *E.g.*, *Chamber of Com. of the U.S.*, 85 F.4th at 779 ("[T]he rule's primary benefit—decreasing investor uncertainty about motivations underlying buybacks—is inadequately substantiated.").

c. HRSA never responded to comments explaining that the drug companies vastly overstate the duplicate discount problem and that, based on HRSA's own audit data, duplicate discounts have decreased dramatically since 2018. *See Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018) (an agency "cannot ignore evidence that undercuts its judgment; and it may not minimize such evidence without adequate explanation").

d. HRSA "inconsistently and opportunistically framed the costs and benefits of the rule," *Bus. Roundtable,* 647 F.3d at 1148–49, by comparing the Program's administrative and other costs to *overall* 340B Program-wide duplicate discounts rather than the *incremental* benefits of its 25-drug Rebate Program.

E.g., Chamber of Com. of the U.S., 85 F.4th at 777 (an agency "cannot have it both ways" by embracing a premise when tallying benefits and rejecting it when tallying costs).

21. Ultimately, the Notice follows a consistent, and telling, pattern. Again and again, covered entities "offered ample basis for the truth of their positions: their extensive knowledge and experience with" hospital operations under the 340B Program. *Cath. Legal Immigr. Network, Inc. v. EOIR*, 513 F. Supp. 3d 154, 174 (D.D.C. 2021). These covered entities are "intimately familiar with their budgets and resources and therefore have a unique capacity to estimate how" the Rebate Program "would upend their normal practices and would affect the number of [patients] they can serve." *Id*. But HRSA flatly dismissed their comments and declared that it "anticipates," "expects," and "believes" the burdens will be small. 91 Fed. Reg. at 48,891, 48,893–95. By contrast, whenever drug companies and their vendors supplied assertions, HRSA uncritically adopted them as fact. That is precisely the kind of "unquestioning reliance" on a regulated party's self-serving analysis that courts forbid. *Susquehanna Int'l Grp., LLP v. SEC*, 866 F.3d 442, 447 (D.C. Cir. 2017).

22. HRSA's treatment of reliance interests fares no better under the APA. Despite having previously "agree[d]" that covered entities' reliance interests are "significant," *AHA II*, 164 F.4th at 34, HRSA has now declared them unreasonable as a "matter of law," 91 Fed. Reg. at 48,889. In its view, because the statute gives HRSA discretion to approve a rebate mechanism in certain circumstances, covered entities could not rely on thirty-three years of consistent practice and repeated agency endorsement of the upfront discount model. Under Supreme Court and First Circuit precedent, that reasoning fails as a matter of law. *E.g.*, *Dep't of Homeland Sec. v. Regents*

of the Univ. of Cal., 591 U.S. 1, 30–32 (2020); *Woonasquatucket River Watershed Council v. U.S. Dep't of Agric.*, 186 F.4th 25, 44–46 (1st Cir. 2026).

23. HRSA also failed to rationally consider obvious, less burdensome alternatives. This is particularly stunning because Defendants told the First Circuit last year that "[m]anufacturers have alternate means to deduplicate discounts," Doc. 00118385034 at 8, No. 25-2236, *Am. Hosp. Ass'n v. Kennedy* (1st Cir. 2025), and said the same to the D.C. Circuit as recently as February 2026. Doc. 2158427 at 2, No. 25-5177, *Novartis Pharms. Corp. v. Kennedy* (D.C. Cir. 2025). Yet the Notice rejects a neutral data clearinghouse in a single paragraph, 91 Fed. Reg. at 48,900, even as its sister agency, the Centers for Medicare and Medicaid Services ("CMS"), opened a similar clearinghouse on October 1, 2026, the same day HRSA announced the drug company application approvals for the Rebate Program. In addition, HRSA rejected every alternative that preserves upfront discounts based on the self-justifying logic that such alternatives "would not inform whether rebates are an efficient means" of providing 340B pricing. *Id.* at 48,890. It also ignored altogether the AHA's proposals that drug companies publish 340B and maximum fair prices prospectively, that drug companies fund the costs of any "test" they want to run, and that any pilot be deferred until after safety-net hospitals absorb the $68 billion revenue impact of the OBBBA.

24. Most fundamentally, HRSA evaluated the Rebate Program under the wrong legal standard. Congress committed the choice of pricing mechanism to Defendants with an express instruction: use "the mechanism that is the most effective and most efficient *from the standpoint of each type of 'covered entity.*'" H.R. Rep. No. 102-384, pt. 2, at 16 (1992) (emphasis added). HRSA quoted the "standpoint" standard in several legal filings over the last two years, and it applied that standard previously to another type of covered entity. *See infra* ¶¶ 51, 54–56. The D.C. Circuit repeatedly emphasized that standard just days before HRSA issued its Notice.

Novartis Pharms. Corp. v. Kennedy, 182 F.4th 1027, 1030–31 (D.C. Cir. 2026). HRSA's Notice itself even quotes this "standpoint" standard. *See* 91 Fed. Reg. at 48,884–85.

25. But HRSA never *applied* that "standpoint" standard. Instead, HRSA announced that it "must balance" covered entities' interests against "program integrity" and "competing policy concerns," *id.* at 48,887–88—a standard of the agency's own invention that elevates a "subsidiary" nonstatutory goal over the particular statutory purpose made explicit by Congress, *see PhRMA v. Frey*, 2026 WL 184504, at *9 n.10 (D. Me. Jan. 23, 2026). The reason is obvious: a payment mechanism that imposes *at least* half a billion dollars—and, more realistically, *billions* of dollars—in annual costs on safety-net providers is neither effective nor efficient from the standpoint of the covered entities. The Rebate Program was not based on the relevant factors and was "unmoored from the purposes and concerns" of the relevant law. *Judulang v. Holder*, 565 U.S. 42, 64 (2011); *Gulluni v. Levy*, 85 F.4th 76, 82 (1st Cir. 2023).

26. Thousands of 340B hospitals and other 340B providers face crushing costs and consequences should the Rebate Program go into effect as intended on January 1, 2027, jeopardizing their ability to provide care to the most vulnerable patients in their communities. Many of these safety-net hospitals provide the only healthcare services in their areas. For covered entities to continue providing their current levels of care to their patients, this Court must quickly enjoin this unlawful, unnecessary, and unexplained program that jeopardizes one of the key pillars of U.S. healthcare. The Rebate Program is arbitrary and capricious and must be set aside.

Parties

27. Plaintiff AHA is a nonprofit trade association representing hospitals, healthcare systems, networks, and other providers of care. Its principal place of business is in Chicago, Illinois. AHA represents its members, including Eastern Maine Medical Center, Nathan Littauer

Hospital & Nursing Home, Unity Medical Center, and Dallas County Medical Center, in this action. More than 2,000 of the AHA's member-hospitals participate in the 340B Program. Those members will have no choice but to participate in the Rebate Program and are therefore aggrieved by Defendants' decision to implement that Program, including the decision to implement it by the January 1, 2027 effective date. Protecting those members' interests is germane to AHA's organizational purpose of advancing the health of all individuals and communities, and the individual members' participation is not required to adjudicate the claims for relief.

28. Plaintiff Maine Hospital Association ("MHA") is a nonprofit association that represents 32 community-governed hospitals in Maine. Its principal place of business is in Augusta, Maine. MHA represents its members, including Eastern Maine Medical Center, in this action. Twenty-six of MHA's 32 member-hospitals participate in the 340B Program. Those members will have no choice but to participate in the Rebate Program and are therefore aggrieved by Defendants' decision to implement that Program, including the decision to implement it by the January 1, 2027 effective date. Protecting those members' interests is germane to MHA's organizational purpose of helping its members improve the health of their patients and the communities they serve, and the individual members' participation is not required to adjudicate the claims for relief.

29. Plaintiff Eastern Maine Medical Center ("EMMC") is a nonprofit, 411-bed tertiary medical center and the referral hospital for northern and eastern Maine. It is based in Bangor, Maine, and provides a range of services, including inpatient and outpatient infusion services, primary care, various specialty services, a Level II trauma center, a neonatal intensive care unit, and pediatric services. EMMC is a disproportionate share hospital, and it is one of nine hospitals—and one of eight 340B covered entities—in the Northern Light Health system. EMMC participates

in the 340B Program, prescribes or administers one or more drugs included in the Rebate Program, and therefore will be required to participate in the Rebate Program.

30. Plaintiff Nathan Littauer Hospital & Nursing Home is a nonprofit health system, whose mission is to provide excellent medical care in the communities it serves. It is a New York nonprofit corporation with its principal place of business in Gloversville, New York. Nathan Littauer participates in the 340B Program, prescribes one or more drugs included in the Rebate Program, and therefore will be required to participate in the Rebate Program.

31. Plaintiff Unity Medical Center is a nonprofit health system, whose mission is to provide excellent medical care in the communities it serves. It is a North Dakota nonprofit corporation with its principal place of business in Grafton, North Dakota. Unity Medical Center participates in the 340B Program, prescribes one or more drugs included in the Rebate Program, and therefore will be required to participate in the Rebate Program.

32. Plaintiff Dallas County Medical Center is a nonprofit health system, whose mission is to provide excellent medical care in the communities it serves. It is an Arkansas county-owned entity with its principal place of business in Fordyce, Arkansas. Dallas County Medical Center participates in the 340B Program, prescribes one or more drugs included in the Rebate Program, and therefore will be required to participate in the Rebate Program.

Defendants

33. Defendant Robert F. Kennedy, Jr., is the Secretary of the U.S. Department of Health and Human Services ("HHS"). He is sued in his official capacity.

34. Defendant Thomas J. Engels is the Administrator, Health Resources and Services Administration ("HRSA"), an office within HHS. He is sued in his official capacity.

35. Defendant HHS is a department of the United States government.

36. Defendant HRSA is an HHS agency that administers the 340B Program.

37. The United States of America is named in accordance with 5 U.S.C. § 702. This is an action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer thereof acted or failed to act in an official capacity.

Jurisdiction and Venue

38. This action arises under, and asserts violations of, the APA, 5 U.S.C. §§ 551 *et seq*., and Section 340B of the Public Health Service Act, 42 U.S.C. § 256b. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1346. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other appropriate relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, and the APA, 5 U.S.C. §§ 705–706.

39. Venue lies in this District pursuant to 28 U.S.C. § 1391(e)(1) because Plaintiffs MHA and EMMC reside in the District, Plaintiffs seek relief against federal agencies and federal officials acting in their official capacities, and no real property is involved.

40. This Court may grant relief pursuant to 5 U.S.C. §§ 701–706.

41. Plaintiffs challenge a "final agency action" within the meaning of 5 U.S.C. § 704. To constitute final agency action, a decision "must [1] mark the 'consummation' of the agency's decision-making process—it must not be of a merely tentative or interlocutory nature" and "[2] be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (internal citations omitted).

42. The Rebate Program reflects the consummation of the agency's decision-making process. HRSA announced on August 3, 2026, that it will "implement a rebate approach," making that new Program "effective immediately." 91 Fed. Reg. at 48,883. On October 1, 2026, HRSA

announced the approval of ten drug company applications, corresponding to 18 drugs, to commence on January 1, 2027. *See* HRSA Rebate Program Webpage. That creates real-world consequences for Plaintiffs, their members, and other covered entities. They must either expend immense amounts of capital to comply with the Rebate Program or forgo their ability to purchase certain drugs through the 340B Program and thereby reduce access to care for their patients and communities.

43. HRSA's establishment and implementation of the 340B Rebate Model Pilot Program, as well as its approval of ten drug company applications, are final agency actions that are subject to judicial review under the APA. *See* 5 U.S.C. §§ 704, 706.

The 340B Program

44. Congress created the 340B Drug Pricing Program in 1992 to give safety-net healthcare providers a financial lifeline by allowing them to purchase certain outpatient drugs at discounted prices. When it was enacted, Congress stated that the program's overall purpose was to "enable these 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 (1992); *e.g., Am. Hosp. Ass'n v. Hargan*, 289 F. Supp. 3d 45, 47 (D.D.C. 2017); *PhRMA*, 2026 WL 184504, at *9 & n.10 ("The 340B program is designed to use two other large federal spending programs to incentivize manufacturers to provide a subsidy to healthcare entities caring for underserved patients."). Examples of qualifying covered entities include federally qualified health centers, family planning clinics, state-operated AIDS drug assistance programs, and disproportionate share hospitals, *i.e.*, hospitals that serve a disproportionate share of Medicare, Medicaid, and other low-income and uninsured patients. 42 U.S.C. § 256b(a)(4).

45. Congress incentivized drug manufacturers to participate in the 340B Program by conditioning federal health-insurance coverage of their products on those manufacturers' participation. 42 U.S.C. §§ 1396r-8(a)(1), 256b(a). Specifically, if drug companies decline to provide discounted drugs to safety-net hospitals through the 340B Program, Medicaid and Medicare Part B will not cover the companies' drugs. *Id.* § 1396r-8(a)(1).

46. The 340B Program plays a critical role in ensuring the continued viability of safety-net hospitals and other covered entities. Covered entities generally pay only a fraction of the retail costs of drugs and use those savings to fund their broader caregiving operations. As of 2026, more than 2,700 hospitals participate in the 340B Program.

47. For Plaintiffs like EMMC, Nathan Littauer Hospital, Unity Medical Center, and Dallas County Medical Center, the 340B Program is necessary to their mission, if not their survival. EMMC, for example, has saved tens of millions of dollars through the 340B Program this year, but still operates on negative margins and has done so since 2019. Nathan Littauer Hospital has had negative margins for more than five consecutive years, resulting in a decrease of 58% in its days of cash-on-hand and an increase of 90% in its accounts payable over the past four years. Unity Medical Center's operating margin is just $2.2 million per year, and its 340B savings account for 73% of its 2026 operating margin. Dallas County is similarly situated; it has a margin of only 4.4% and saves more than $1 million annually through the 340B Program. Without their 340B savings, these entities could not maintain their hospital, equipment, and staffing levels, leaving their patients without access to critical services. Plaintiffs are not outliers; the savings provided by the 340B Program are critical to the operations of safety-net hospitals across the country. Hospitals and healthcare providers like these Plaintiffs are the intended beneficiaries of

the 340B Program, and Plaintiffs' experiences are perfect examples of the program functioning precisely the way Congress intended.

HRSA and the Upfront Discount Mechanism

48. HRSA is responsible for administering the 340B Program. HRSA's Administrator is charged with numerous responsibilities under the statute, including the certification of specific categories of covered entities and auditing functions to ensure covered entities have not received duplicate discounts or diverted prescriptions to non-340B patients. 42 U.S.C. § 256b(a)(4)(J)–(K), (a)(5), (7), (9).

49. To effectuate the 340B Program, HRSA's Administrator also enters into an agreement, known as a Pharmaceutical Pricing Agreement ("PPA"), "with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for [such] drugs . . . purchased by a covered entity . . . does not exceed [the ceiling price]." *Id.* § 256b(a)(1). The ceiling price is calculated using a formula that considers each drug's "average" and "best" price in the Medicaid Drug Rebate Program. *Id.* § 256b(a)(1)–(2). Each PPA "require[s] that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.*; *see also* 58 Fed. Reg. 27,289, 27,291 (May 7, 1993). Manufacturers that do not comply with the PPA can be subject to monetary sanctions and even termination from the 340B Program. 42 U.S.C. § 256b(d)(1)(B)(vi).

50. Since the beginning of the 340B Program, HRSA has required drug companies to offer upfront discounts—not rebates—to covered entities. *See id.* § 256b(a)(1); 58 Fed. Reg. at 27,291–92. Covered entities often implement upfront pricing through what is known as the "product-replenishment model." Under this longstanding inventory management model, covered

entities purchase an initial package of drugs at the market price. After confirming a certain quantity of a drug has been sold to 340B-eligible patients, the provider then purchases replacement quantities at the 340B prices. *See PhRMA*, 2026 WL 184504, at *3 (explaining replenishment model). As Defendants described in an August 1, 2025 brief to the D.C. Circuit, "[u]nder this approach, providers obtain an upfront discount for purchases allowing them to get the immediate benefit that the 340B Program is meant to provide." Doc. 2128443 at 2, *Novartis Pharms. Corp. v. Kennedy*, No. 25-5177 (D.C. Cir. Aug. 1, 2025).

51. The sole, narrow exception to the "upfront discount" mechanism is for drugs sold to a certain category of covered entity: AIDS Drug Assistance Programs ("ADAPs"). Because ADAPs' drug-purchasing systems inhibited them from using the "upfront discount" mechanism, HRSA in 1998 recognized that a different payment mechanism was most effective for them. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Rebate Option, 62 Fed. Reg. 45,823, 45,824 (Aug. 29, 1997). HRSA did not extend rebates to any other type of covered entity, finding that (1) "[c]overed entities generally preferred a discount system, because they could negotiate lower prices and needed less initial outlay of drug purchasing money"; and (2) "the [upfront] discount system is functioning successfully for most covered entities[.]" *Id.* at 45,824.

52. Adherence to the "upfront discount" mechanism aligns with Congress's intent for the 340B Program. As the First Circuit explained, covered entities' "financial survival relies on the upfront discounts that they have long received." *AHA II*, 164 F.4th at 34. Forcing rural hospitals and other 340B providers to spend billions of dollars to submit, reconcile, and chase rebates, and to "float" similar amounts to the drug industry each year, puts covered entities at existential risk and endangers the health of their patients and communities. Thus, an "upfront discount"

mechanism is the payment "mechanism that is the most effective and most efficient from the standpoint of each type of 'covered entity.'" H.R. Rep. No. 102-384, pt. 2, at 16 (1992). And it serves the overall purpose of the 340B Program by allowing healthcare providers to use every possible dollar saved from the 340B Program to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," *id*. at 12.

53. HRSA has the authority to approve how drug companies must provide 340B discounts, whether through an upfront discount or a rebate mechanism. *See Novartis Pharms. Corp.*, 182 F.4th at 1029–30. But that authority is not unbounded. "Congress 'd[id] not specify whether 'covered entities' would receive [Section 340B's] favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism' because it 'expect[ed] that the Secretary of HHS, in developing these agreements, w[ould] use the mechanism that is the most effective and most efficient from the standpoint of each type of 'covered entity.'" *Id*. at 1035 (quoting H.R. Rep. No. 102-384, pt. 2, at 16 (1992) (emphasis removed)); *see id.* at 1030 ("The primary House committee report concerning Section 340B acknowledges that optionality and states that the Committee 'expects that the Secretary of HHS, in developing these agreements, will use the mechanism that is the most effective and most efficient from the standpoint of each type of 'covered entity.'" (quoting H.R. Rep. No. 102-384, pt. 2, at 16 (1992))).

HRSA Repeatedly Rejected Drug Companies' Efforts to Move to Rebate Mechanisms

54. For years, HRSA rejected drug company efforts to impose rebate mechanisms, recognizing that they were *not* the "most effective and most efficient" mechanisms for providing discounts from the standpoint of 340B hospitals. Most recently, in 2024, Johnson & Johnson ("J&J"), Eli Lilly, Bristol Myers Squibb, Novartis, and Sanofi each announced plans to require covered entities to purchase certain drugs at the full Wholesale Acquisition Cost ("WAC")—the

highest price at which a manufacturer sells a drug, multiples of the 340B price—and then apply for a rebate after dispensing the drug to a 340B-eligible patient.

55. HRSA promptly blocked any unilateral switch to a rebate mechanism. In September 2024, HRSA warned J&J that its rebate mechanism was unlawful by forcing covered entities "to pay a higher price point up front for every purchase" and requiring them to pay prices exceeding the ceiling price in violation of "Section 340B(a)(1)." 340B_REBATES_000201 at -03, filed in *Eli Lilly & Co. v. Kennedy*, No. 24-cv-3220 (D.D.C. June 5, 2025) (the "*Eli Lilly* Case"), Dkt. 60-1. HRSA threatened to terminate J&J's participation in the 340B Program, *id.* at 340B_REBATES_000212–14, and sent materially identical letters to Eli Lilly, Bristol Myers Squibb, Novartis, and Sanofi, *see, e.g.*, *id.* at 340B_REBATES_000292.

56. The drug companies sued. *J&J Health Care Sys. Inc. v. Kennedy*, No. 24-cv-3188 (D.D.C. filed Nov. 12, 2024); *Eli Lilly & Co. v. Becerra*, No. 24-cv-3220 (D.D.C. filed Nov. 14, 2024); *Bristol Myers Squibb Co. v. Johnson*, No. 24-cv-3337 (D.D.C. filed Nov. 26, 2024); *Sanofi-Aventis U.S. LLC v. HHS*, No. 24-cv-3496 (D.D.C. filed Dec. 16, 2024); *Novartis Pharms. Corp. v. Becerra*, No. 25-cv-117 (D.D.C. filed Jan. 15, 2025). In defending those suits, HRSA and HHS repeatedly defended the "upfront discount" mechanism:

a. In their April 2025 motion for summary judgment in the *J&J* litigation, HRSA and HHS noted that HRSA "has long envisioned upfront discounts as the preferred price reduction mechanism, noting that '[c]overed entities generally preferred a discount system, because they could negotiate lower prices and needed less initial outlay of drug purchasing money.'" Dkt. 41-1 at 18, *J&J*, No. 24-cv-3188.

b. HHS and HRSA further emphasized that "[t]he Agency [HRSA] would neglect its duty if it did not consider all aspects of the problem, including . . . how the changes would affect

the operations of covered entities and the wellbeing of patients who rely on 340B drugs, before allowing manufacture[r]s to redesign the operation of the program." *Id.* at 20.

c. In an August 2025 D.C. Circuit brief, HHS and HRSA further defended upfront discounts and flagged concerns with a rebate mechanism. "Unlike 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. v. Kennedy*, No. 25-5177.

57. District courts agreed that HRSA could bar a unilateral rebate mechanism, crediting HRSA's explanation that covered entities would otherwise "be forced to incur higher carrying costs for these drugs, essentially floating revenue to drug manufacturers." *Johnson & Johnson Health Care Sys. Inc. v. Kennedy*, 2025 WL 1783901, at *12 (D.D.C. June 27, 2025) (internal quotation marks omitted); *see also Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630, at *12 (D.D.C. May 15, 2025). On July 21, 2026—thirteen days before HRSA released the Notice central to this case—the D.C. Circuit affirmed, repeatedly emphasizing Congress's instruction that the Secretary select the mechanism "most effective and most efficient from the standpoint of each type of 'covered entity.'" *Novartis Pharms. Corp.*, 182 F.4th at 1030–31.

HRSA Unlawfully Tried to Implement a Rebate Program in 2025

58. On July 31, 2025—at the same time government attorneys representing Defendants were highlighting the risks of a rebate mechanism in federal courts—HRSA abruptly announced a "340B Rebate Model Pilot Program" by press release, followed by a corrected Federal Register notice on August 7, 2025, 90 Fed. Reg. 38,165 (the "2025 Notice").

59. The 2025 Notice offers almost no justification for switching to a rebate mechanism. It only cites "inquiries" from drug companies about deduplicating 340B discounts and the new Medicare "Maximum Fair Prices" negotiated under the Inflation Reduction Act ("IRA"), 42 U.S.C. § 1320f *et seq.* The 2025 Notice contained no estimate of the costs of compliance, no

acknowledgment of covered entities' reliance interests, no discussion of reasonable and less costly alternatives, and no acknowledgment of the financial harms HRSA itself had described to drug companies and the courts months earlier.

60. On December 1, 2025, Plaintiffs (except for EMMC) sued in this Court and moved for a temporary restraining order and preliminary injunction. Compl., *Am. Hosp. Ass'n v. Kennedy*, No. 2:25-cv-600 (D. Me. Dec. 1, 2025), Dkt. Nos. 1, 3. By then, HRSA had approved nine drug companies' applications covering ten drugs, after receiving 1,243 public comments on the 2025 Notice. 91 Fed. Reg. at 48,885.

61. On December 29, 2025, Chief Judge Walker granted a preliminary injunction and preliminarily set aside those approvals. *AHA I*, 820 F. Supp. 3d 30. The Court identified multiple independent APA violations. *First*, there was "no evidence in the administrative record that Defendants considered Plaintiffs['] significant reliance interests," a failure "alone fatal to the Rebate Program." *Id.* at 45. *Second*, Defendants had not calculated what the Rebate Program would cost before adopting it—a defect this Court also found to be "[f]atal to Defendants . . . under the APA." *Id. Third*, the Court found the record "silent on the cost of floating the full price of covered drugs" and held that Defendants were owed no deference on that question because "financial forecasts about what costs the 340B entities can bear for a certain period is not predicated on any specialized or expert knowledge of the Agency." *Id.* (citing *FCC v. Nat'l Citizens Comm. for Broad.*, 436 U.S. 775, 815 (1978)).

62. Defendants appealed and sought a stay. This Court denied a stay on December 30, 2025, Dkt. No. 96; the First Circuit denied an administrative stay on December 31, 2025; and the First Circuit denied a stay pending appeal on January 7, 2026. *AHA II*, 164 F.4th at 33 n.1, 37. The First Circuit found "the administrative record does not reveal any prior consideration of the

significant costs that safety-net hospitals will incur under the Rebate Program," pointing to the federal government's concession "that it was 'currently examining' the hospitals' increased administrative costs from the Rebate Program." *Id.* at 34. The appellate court also recognized that HHS had "historically rejected such proposals as both inferior to Section 340B's current upfront-discount model and disruptive to safety-net hospitals." *Id*. at 32.

63. Defendants did not attempt to further defend the 2025 Rebate Program. On January 20, 2026, the First Circuit granted Defendants' motion to dismiss their own appeal, and on February 10, 2026, this Court vacated the Program and remanded to HHS—setting aside the "340B Program Notice: Application Process for the 340B Rebate Model Pilot Program," 90 Fed. Reg. 36,163 (Aug. 1, 2025), its Correction, 90 Fed. Reg. 38,165 (Aug. 7, 2025), and Defendants' approvals of the drug companies' applications submitted pursuant to those notices. Order, *AHA I*, No. 2:25-cv-600 (D. Me. Feb. 10, 2026), Dkt. Nos. 114, 115.

64. Ultimately, both courts faulted Defendants for the same basic failure: committing to a rebate mechanism without having calculated what it would cost the hospitals required to operate it and, therefore, not having "identif[ied] 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). As set forth below, Defendants have again made the same error, among others.

A Week After the 2025 Rebate Program Was Vacated, HRSA Hastily Started Again

65. Seven days after the vacatur, HRSA started over. On February 17, 2026, the agency published its RFI, inviting comments on a wide range of topics:

a. HRSA asked covered entities to submit estimates of the incremental "administrative and operational" costs they would bear under a rebate program, including both "one-time startup costs" and "ongoing costs." 91 Fed. Reg. at

7,289–90. It asked, for example, if (a) a rebate program "would require additional full-time employees"; (b) "any new or modified IT systems, software, or data infrastructure" would be required and at what cost; and (c) "any prompt payment incentives or discounts were currently offered by drug wholesalers for early payment and the timeframes associated with those incentives." *Id*. It also sought comments about "additional costs," including "reduction in services offered" and "impacts on access to drugs for patients." *Id*. at 7,289.

b. HRSA also showed clear awareness of potential float costs, asking commenters to "[d]escribe with specificity whether payment timing (e.g., within ten calendar days of submission of a complete claim) . . . would affect your cash flow, including any financial risks to your organization." *Id.* at 7,289–90.

66. Critically, however, nowhere does the RFI directly ask the operative question required under the 340B statute: whether a rebate mechanism is the "most effective and most efficient" *from the standpoint of the covered entity*. H.R. Rep. No. 102-384, pt. 2, at 16 (1992) (emphasis added). HRSA instead asked how to "balance" the covered entities' interests against the drug companies' interests.[1] *Id.* at 7,289.

HRSA Published an Inaccurate Cost Estimate Months Before Receiving Any Comments

67. Nearly two months before comments on the RFI were due, HRSA published an estimate of the Rebate Program's burden in the February ICR, as required by the Paperwork Reduction Act ("PRA").

[1] HRSA initially allowed thirty days for comment, setting a deadline of March 19, 2026. 91 Fed. Reg. at 7,291. On February 26, 2026, HRSA extended that deadline to April 20, 2026. Request for Information: 340B Rebate Model Pilot Program; Extension of Comment Period, 91 Fed. Reg. 9,632 (Feb. 26, 2026).

a. The ICR estimates that 14,600 covered entities making 52 claims-data submissions each year, at five hours per submission, would result in a total of 3,796,000 annual burden hours for covered entities. 91 Fed. Reg. at 9,633. As discussed *infra* ¶¶ 124–25, 145, HRSA would later confirm these hours would cost safety-net entities well over $500 million per year.

b. By contrast, HRSA estimated just 416 *total* hours for all thirteen participating drug companies—104 hours to prepare rebate model plans and 312 hours total to submit monthly reports. *Id.*

68. HRSA never explained how it arrived at its 5-hour-per-week assumption, but the provenance of the 5-hour figure is simple. For the 2025 Rebate Program, HRSA selected (without explanation) a burden estimate of two hours per week in its PRA filings. Hundreds of commenters challenged that 2-hour estimate during the multiple comment periods in 2025, and Plaintiffs showed in the prior litigation that HRSA never vetted its 2-hour estimate. Mot. for TRO at 13, No. 25-cv-600 (D. Me. Dec. 1, 2025), Dkt. No. 3; Compl. ¶¶ 63–71, No. 25-cv-600 (D. Me. Dec. 1, 2025), Dkt. No. 1; *AHA I*, 820 F. Supp. 3d at 44 ("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.'"). Nevertheless, with HRSA now having proposed to increase the number of covered drugs in the new Program by a factor of 2.5 (from 10 proposed drugs in 2025 to 25 proposed drugs in 2026), HRSA simply multiplied that prior 2-hour estimate by 2.5 to arrive at 5 hours.

69. Over the ensuing months, the administrative record amassed extensive firsthand evidence from hospitals, clinics, and other safety-net providers that would have to implement the Rebate Program. That evidence showed not only that HRSA had substantially understated the administrative burden, but also that the Program would impose overall annual administrative costs exceeding $1 billion for 340B hospitals alone and thereby threaten patient care. HRSA refused, however, to engage with that evidence, and this 5-hour-per-week contrivance remained the entirety of the cost estimate underpinning its analysis of the Rebate Program.

Commenters Detailed Enormous Costs and Harms for Safety-Net Entities

70. By the time the comment period closed on April 20, 2026, HRSA had received 2,475 comments—more than twice the number submitted the year before. *See* Notice, 91 Fed. Reg. at 48,888. Covered entities submitted detailed, empirical, firsthand evidence addressing HRSA's proposed questions and identifying additional consequences the RFI had not accounted for. Over 600 comments supplied facility-specific dollar figures, staffing plans, wholesaler contract terms, financing costs, bond covenant thresholds, other lost discounts, or additional data documenting the costs of implementing a rebate mechanism. Covered entities also detailed their experience under a separate HHS program showing that HRSA misunderstood how rebates work in practice.

71. The comments also challenged HRSA's asserted justification for imposing those costs. Covered entities submitted evidence that drug companies and their proxies had substantially overstated the prevalence of duplicate discounts, undermining the asserted benefit of a rebate mechanism. They also noted a wide range of alternative approaches to a rebate mechanism that would achieve the agency's goals at lower costs, none of which HRSA meaningfully considered.

The Staggering Administrative Costs of a Rebate Program

72. Commenters demonstrated that the administrative costs of a rebate mechanism, even one limited to the drugs selected under the Medicare Drug Price Negotiation Program ("MDPNP"), would exceed $1 billion annually just for the approximately 2,728 340B hospitals. *See generally* HRSA-2026-0001-1846 (comment letter of Plaintiff AHA) ("AHA Letter"); HRSA-2026-0001-1994 at 1 (America's Essential Hospitals providing that, "[o]verall, we estimate continuing HRSA's proposed rebate model would result in $1.5–1.6 billion in direct costs and $3.7–$4.6 billion in total costs for hospitals in 2027 alone."). This number *excludes* the costs for the roughly 12,500 covered entities that are not hospitals. Those administrative costs fall into distinct categories, each of which was documented in the record.

73. **Labor Costs**: Commenters explained that HRSA's 5-hour-per-week assumption does not accurately measure the *total* labor a rebate mechanism requires. Commenters identified two problems with this approach. *First*, HRSA had badly understated the one labor cost it attempted to measure. *Second*, overall labor costs include several additional categories: back-end reconciliation, dispute and denial management, information-technology work, cybersecurity protection, training, and so on. The comments explained that the real labor burden of a Rebate Program is many multiples of HRSA's 5-hours-per-week assumption.

74. Plaintiff AHA, for example, gathered input from its member hospitals on the additional staffing a rebate program would require. Its members reported that, on average, complying with the Program—including managing data entry, handling inputs, reconciling rebates and claims, resolving rebate disputes, and more—would conservatively require them to hire at least one new full-time employee, amounting to an additional 40 hours per week, not 5. *See* AHA Letter at 7–8. Likewise, the nonprofit Association of American Medical Colleges ("AAMC")

reported, based on its own member research, that the staff time required for submitting and reconciling claims and managing disputes and discrepancies alone "is estimated to require 25 to 40 hours per week," involving personnel not only in pharmacy but also in legal, compliance, revenue-cycle, and finance. HRSA-2026-0001-1914 at 10.

75. Covered entities of every size reported that they cannot absorb a rebate mechanism with existing staff. For example, nearly half (47%) of community health centers that responded to a National Association of Community Health Centers member assessment reported that they would need to hire an additional 0.5 to 1 full-time employee ("FTE"), more than a third (36%) would need 1 to 2 additional FTEs, and 7% would need more than two. *See, e.g.*, HRSA-2026-0001-2011 at 5 (comments of HopeHealth, citing member assessment). Likewise, a Georgia Hospital Association survey of members showed, among other things, "[i]ncremental administrative costs ranging from $100,000 to more than $530,000 annually" and an average of "[o]ne to 1.5 additional Full Time Equivalent (FTE) administrative positions[.]" HRSA-2026-0001-1894 at 2. And a Massachusetts Health & Hospital Association survey of members showed, among other things, "70% of respondents anticipate hiring more than 10 new FTEs at a cost of $1.3 million to assist with the rebate process[.]" HRSA-2026-0001-2007 at 2.

76. Small and rural hospitals reported the same need. St. Tammany Health System, a community-owned health system in Covington, Louisiana, reported "an additional 2.0 FTEs would be required." HRSA-2026-0001-0080 at 2. Graham County Hospital, a rural critical access hospital in Hill City, Kansas, reported "[a] minimum of 1.5 additional FTEs." HRSA-2026-0001-0048 at 3; *see also* HRSA-2026-0001-1564 at 2 (Knox Community Hospital, a rural community hospital in Mount Vernon, Ohio, calling HRSA's 5-hour estimate "ludicrously low"); HRSA-2026-0001-1522 at 2–3 (North Shore Health, a critical access hospital in Grand Marais, Minnesota, noting

that "[NSH] does not currently have sufficient staff to comply with a rebate-based system. Our pharmacy services are provided by two pharmacists who already operate at capacity. Even a modest increase in workload would be unsustainable. Recruiting additional qualified professionals in our rural location is extremely challenging and additional burdens could lead to staff attrition, further limiting available services.").

77. Larger systems reported larger burdens. Yale New Haven Health estimated approximately three FTEs. HRSA-2026-0001-1473 at 1–2. Vanderbilt Health projected six FTEs, or 240 hours per week, "48 times greater than HRSA's estimate." HRSA-2026-0001-1593 at 3. Equitas Health, a nonprofit community health center system based in Columbus, Ohio, projected six to seven. HRSA-2026-0001-0073 at 2. Baylor Scott & White Health, a nonprofit health system in Texas, projected "seven to eight FTEs and . . . hundreds of hours a month on program compliance and operations." HRSA-2026-0001-1485 at 1. Tarrant County Hospital District, the public safety-net hospital system in Fort Worth, Texas, calculated that it would require approximately 5,000 labor hours for tracking alone before any denials, appeals, contract complexity, or auditing. HRSA-2026-0001-1827 at 5. New York City Health + Hospitals, the nation's largest public hospital system, explained that "[t]he reality is that our organization would face in excess of 100 additional administrative hours per week, not five." HRSA-2026-0001-2021 at 4.

78. Other individual safety-net providers filled the record with similar data. The Richland Hospital, a rural critical access hospital in Wisconsin, estimated ongoing costs "of at least 40 hours and thousands of dollars per month." HRSA-2026-0001-0093 at 2. Saint Peter's University Hospital, a nonprofit teaching hospital in New Brunswick, New Jersey, estimated that fully staffing a rebate program would require twelve employees at approximately $1 million per

year. HRSA-2026-0001-0111 at 2. Ventura County Medical Center, a county-owned safety-net hospital in California, estimated $300,000–$410,000 in annual personnel costs. HRSA-2026-0001-2117 at 3. Ammonoosuc Community Health Services, a federally qualified health center serving rural northern New Hampshire, "anticipates adding 1–2 FTE that alone would put the program out of existence for all intents and purposes where the cost of administration will exceed the cost of any savings." HRSA-2026-0001-0304 at 7 (emphasis removed). Morris County Hospital, a county-owned, nonprofit, 21-bed critical access hospital in Council Grove, Kansas, informed HRSA that "alter[ing] this [upfront discount] structure with having to manually account for . . . individual rebates . . . will turn our 340B program into a workflow quagmire" and estimated that it would require 2 FTEs, at an annual cost of $104,000. HRSA-2026-0001-2455 at 2–3.

79. As these and other commenters explained, HRSA's gross undercalculation of labor costs had several sources. *First*, HRSA assumed that front-end data entry would be relatively expedited and could be collected from a single source. The reality, as commenters explained, is that the required data elements do not exist in one place and are housed across electronic health records, split-billing software, third-party administrator ("TPA") platforms, wholesaler portals, and finance systems. Significant staff hours would be consumed each week pulling data from various locations, building and verifying separate reports, and validating data integrity across systems with differing package sizes and National Drug Code ("NDC") configurations. *See, e.g.*, AHA Letter at 12–13. For example, University of California Health, the academic health system of the University of California, reported that blank payer-ID and National Provider Identifier ("NPI") fields must be manually populated and units of measure manually overridden before every submission. HRSA-2026-0001-1986 at 5; *see also* HRSA-2026-0001-2071 at 5 (Medical University of South Carolina explaining that "[r]elevant data may reside across the EHR, split-

billing platforms, revenue cycle systems, payer claims systems, wholesaler data, and TPA platforms" and that "[p]articularly for medical claims data, substantial manual work would likely be required"); HRSA-2026-0001-2013 at 6 (comment from Memorial Health System, a small rural critical access hospital in Kansas, that "the necessary data elements exist in different internal systems," that "[t]hese systems do not currently operate through a single automated data feed," and that "[o]ur hospital's systems were not designed to automatically transmit all of the required data elements directly to our third-party administrator (TPA) or other rebate-processing entities").

80. *Second*, HRSA entirely omitted the work that must occur when rebate payments come back to covered entities. Commenters explained that this back-end reconciliation, a category of labor that does not exist under an upfront discount mechanism, will likely be the single most time-consuming and costly component of the program. *See, e.g.*, AHA Letter at 14–16. For example, Legacy Health, a nonprofit healthcare provider serving Oregon and southwest Washington, noted "the increase in administrative burden . . . would be driven by the need to implement rebate reconciliation workflows and not primarily in the data submissions themselves." HRSA-2026-0001-1710 at 2–3. Likewise, Abbeville Area Medical Center, a South Carolina rural critical access hospital, explained that "[r]econciliation is the biggest concern with the increased administration cost" because "[t]here are thousands of prescriptions that are run daily and a person or TPA would need to verify the rebate had been performed." HRSA-2026-0001-1652 at 2–3. And West Virginia United Health System explained that "[t]racking rebate payments by manufacturers, matching payments back to submitted claims, reconciling, resolving good faith inquiries, reconciliation of payments, and maintaining the audit trail can easily exceed the [submission] work itself." HRSA-2026-0001-1843 at 4.[2]

[2] *See also* HRSA-2026-0001-2174 at 5–6 (University Health / Bexar County Hospital District, a public safety-net hospital system in San Antonio, estimating 1–2 additional hours per week of manual claims submission but 133

81. These commenters explained that under a rebate mechanism, hospitals must match payments received weeks or months later to individual drug purchases and claims. They also must identify claims for which rebates are missing, delayed, denied, or underpaid; investigate discrepancies between the entity's records and manufacturers' determinations; correct or resubmit claims where appropriate; and pursue unresolved amounts with manufacturers or their vendors. Hospitals also explained that rebate reconciliation creates substantial accounting and allocation burdens once a rebate payment is received. They must determine which underlying 340B transactions the payment covers, match those transactions to their own purchasing and claims records, and then allocate the payment to the appropriate internal accounts, facilities, departments, pharmacies, cost centers, or other business units. These are not merely bookkeeping formalities. They require coordination among pharmacy, finance, accounting, revenue-cycle, and information-technology personnel. In addition, because some drug companies may make lump-sum rebate payments covering many claims, hospitals will have to perform additional work simply to determine whether they were paid at all. *See* AHA Letter at 14 & n.18.

82. Hospitals' experience with analogous platforms confirmed the point. Pella Regional Health Center, a rural critical access hospital in Iowa, reported that its experience with manufacturer data-submission platforms "has been rife with costly challenges" so severe that it has assigned staff to do nothing but resolve them. HRSA-2026-0001-0296 at 3. Premier, Inc. reported that CMS's platform for the first IRA drugs "often misclassifies" claims and that its appeals process is so "complex and time intensive" that "several hospitals have been forced to

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additional hours per week for claims reconciliation, excluding dispute resolution, audit preparation, and manufacturer coordination); HRSA-2026-0001-1830 at 4 (UMC Health System, a public teaching hospital system in Lubbock, Texas, concluding that "[u]nder a rebate-based 340B model, we would face an untenable choice: either forgo rebates entirely because reconciliation is too burdensome to complete, or hire additional staff simply to access the same—or potentially less—cost savings"); HRSA-2026-0001-1600 at 1 (Family HealthCare Center, a community health center in Fargo, North Dakota, reporting that it anticipates spending approximately $300,000 for manual reconciliation alone).

redirect existing staff or hire new FTEs to manage errors and appeals." HRSA-2026-0001-0662 at 3. Others described "[m]anually opening each claim" because there is "no bulk view available," HRSA-2026-0001-1421 at 3, and the "[i]nability to correlate anonymized claims data" between platforms, HRSA-2026-0001-0663 at 1. *See also* HRSA-2026-0001-0160 at 1.

83. Some comments noted that HRSA's omission of back-end reconciliation costs seems to have been due to the agency wrongly making burden assessments by looking at a *different* data-sharing program, the 340B Enhanced Services Platform ("340B ESP"). Commenters emphasized that, unlike a rebate mechanism, 340B ESP involves no post-submission payment reconciliation whatsoever, so nothing in covered entities' current operations resembles 340B ESP's workload. *See* AHA Letter at 16; *see also* HRSA-2026-0001-0048 at 4 (Graham County Hospital explaining "[t]he data we provide today through 340B ESP and payers for billing purposes does not include the detailed financial reconciliation and rebate tracking elements required under a manufacturer rebate framework.").

84. *Third*, commenters documented that information-technology and cybersecurity labor is a distinct cost from just the pharmacists included in HRSA's analysis. *E.g.*, AHA Letter at 7 n.6; HRSA-2026-0001-1914 at 11 (comment from AAMC that "IT/data integration analysts" were among the permanent roles members have filled or expect to fill). Temple University Hospital, an academic safety-net hospital in Philadelphia, for example, explained that implementation would require a dedicated IT/accounting professional as one of two new FTEs, with each additional pair of FTEs costing $302,000 per year as drugs are added in 2027. HRSA-2026-0001-1396 at 5–6.

85. **Recurring Non-Labor Administrative Costs:** Commenters separately quantified non-labor operational costs—vendor and TPA fees, software, IT support, and financial auditing

services—"rang[ing] from $150,000 to over $750,000 per hospital" annually, "with costs increasing further if there are significant delays and denials with the rebate payments." AHA Letter at 9. Even using the bottom of that range—just $150,000 per hospital—across 2,728 340B hospitals yields more than $400 million in additional annual costs, pushing the total administrative burden on 340B hospitals alone above $1 billion each year. *Id.* at 9–11.

86. Those costs include new software and IT services—$30,000 to $50,000 per year for smaller entities and multiples of that for larger ones. Saint Peter's University Hospital estimated approximately $500,000 per year for rebate billing and tracking software alone. HRSA-2026-0001-0111 at 2. Tarrant County Hospital District estimated $100,000 to $250,000 per year in ongoing TPA fees and $40,000–$120,000 per year in IT maintenance and enhancements. HRSA-2026-0001-1827 at 3; *see also* HRSA-2026-0001-2021 at 6 (New York City Health + Hospitals commenting that "[o]ngoing expenses would include system maintenance, vendor licensing fees, data storage, interface management, cybersecurity enhancements, and continuous updates to reflect evolving program requirements," plus "recurring personnel costs for IT support and data management staff required to sustain these systems").

87. Commenters also documented new costs associated with "compliance and audit process changes to prepare for increased audits related to rebate models," "expanded audit and risk management controls," and dedicated compliance personnel. HRSA-2026-0001-1914 at 10–12 (comment of AAMC); *see also* HRSA-2026-0001-1827 at 2–3 (Tarrant County Hospital District estimates $20,000–$50,000 in one-time legal and compliance review costs, including audit preparation, plus $50,000–$120,000 per year in ongoing compliance and audit support); HRSA-2026-0001-0046 at 2–3 (Rooks County Health Center, a 22-bed critical access hospital in

Plainville, Kansas, estimates $5,000–$10,000 per year for audit preparation and support and another $5,000–$10,000 per year for ongoing legal and compliance review).

88. **Start-Up Costs:** Commenters separately identified significant one-time costs to build the infrastructure that a rebate mechanism requires. These included "claims mapping, interfaces, and secure data transmission of claims information to manufacturers"; redesigned finance and accounting systems "to allow for receivables tracking and reconciliation processes"; training; and "expanded audit and risk management controls." HRSA-2026-0001-1914 at 12. As the AHA explained, "even before the new claims and reconciliation process begins, many hundreds of staff hours must be spent across the entire hospital organization to prepare for a new discount mechanism." AHA Letter at 15. These "one-time costs are significant" and are sunk regardless of whether HRSA's "purported 'test'" succeeds. *Id.*

89. Individual covered entities quantified those costs, from tens of thousands of dollars at the smallest hospitals to millions at large systems. Bitterroot Health, a rural hospital in Hamilton, Montana, calculated $95,000 to $185,000 in one-time costs. HRSA-2026-0001-0058 at 3. Memorial Community Hospital, a critical access hospital in Blair, Nebraska, similarly expected up to $300,000 in start-up costs. HRSA-2026-0001-0105 at 1. The University of Vermont Health Network reported "an upfront cost between $3,000,000 to $4,000,000" for itself only. HRSA-2026-0001-1720 at 2; *see also* HRSA-2026-0001-1369 at 2 (Coffee Regional Medical Center, a rural nonprofit hospital in Douglas, Georgia, estimating costs "effectively doubling our current 340B administrative spend"); HRSA-2026-0001-1438 at 2 (Wabash General Hospital, a rural critical access hospital in Mount Carmel, Illinois, reporting upfront costs of $122,000 to $178,000). MultiCare Health System, a nonprofit health system based in Tacoma, Washington, reported that it had *already incurred* "approximately $60,000 in preparatory expenses for the rebate program

between Oct. 1 and Dec. 21, 2025" for the original ten drugs, plus one new FTE, such that its "total startup expenditure for the first ten rebate drugs under just the Medicare program approached $200,000." HRSA-2026-0001-2251 at 2.

Comments Detailed That the Various "Float" Costs Carried Independent and Significant Harms

90. Commenters also demonstrated, with specificity, why requiring covered entities to pay WAC while awaiting a rebate imposes severe costs, even under the nominal 10-day payment period proposed in the failed 2025 Rebate Program. 91 Fed. Reg. at 48,895.

91. Commenters gave specific calculations of how much more money safety-net hospitals and other covered entities would need to pay upfront for these drugs. Trinity Health, the Catholic Health Ministries-sponsored national system that includes 39 340B facilities, explained that its system currently spends approximately $26 million annually on the 25 drugs contemplated for the Rebate Program, but that under a Rebate Program "purchasing these same drugs in the current quantities at the much higher Wholesale Acquisition Cost (WAC) would increase the purchase price to $671M annually." HRSA-2026-0001-1627 at 3. Dallas County Hospital District, a Texas public safety-net hospital system, reported that its current acquisition cost of the 25 drugs is $9.3 million with current 340B pricing, but under the Rebate Program would cost $96 million (a $237,000-per-day carrying cost). HRSA-2026-0001-2068 at 3. The University of California health system calculated an increased outlay of $120 million for the ten drugs included in the enjoined 2025 Rebate Program, HRSA-2026-0001-1986 at 5, and the Ohio State University Wexner Medical Center calculated an increased cost of approximately $30 million for the same, HRSA-2026-0001-2057 at 11.

92. Smaller and rural facilities reported that they would face similar many-fold increases in acquisition costs. Southern Nevada Community Health Center, a federally qualified

health center in Las Vegas, Nevada, estimated it would cost $130,000 per month to purchase the ten original pilot drugs at WAC, compared to less than $1,000 per month at the 340B price. HRSA-2026-0001-1604 at 9. Glacial Ridge Health System, a critical access hospital in Glenwood, Minnesota, reported that the Rebate Program would drive the acquisition costs of 340B drugs from $431,272 to $1,776,653—an additional $1,345,381 cost that it said "is not manageable." HRSA-2026-0001-1503 at 1. Kent County Memorial Hospital, a 359-bed hospital in Warwick, Rhode Island, explained that for the 25 covered drugs it would have to advance approximately $25.7 million in additional upfront acquisition costs. HRSA-2026-0001-1624 at 4; *see also* HRSA-2026-0001-1773 at 1, 8 (Family Health Services of Darke County, a health center serving rural Ohio, noting that under the Rebate Program it would have $1 million in cash "frozen" in manufacturers' systems in 2026, rising to $1.3 million in 2027 and $2 million in 2028).

93. **The Inadequacy of a 10-Day Guardrail:** Many commenters explained why HRSA's prior proposal requiring drug companies to reimburse covered entities within 10 days of submission would not protect them from the Rebate Program's various "float" costs.

94. *First*, commenters explained that many wholesalers required payment in less than 10 days, meaning the 10-day deadline would not allow covered entities to avoid floating the WAC. The University of Arkansas for Medical Sciences explained that it "typically remits payment within 5 calendar days under current wholesaler terms." HRSA-2026-0001-0065 at 11. Clark Fork Valley Hospital, a community hospital located in Plains, Montana, commented that "pharmacy distributors already apply the most onerous payment terms on our hospital of any other vendor we deal with, at 7 days," and "they will not hesitate to cut off drug shipments if they are not paid on time." HRSA-2026-0001-1601 at 3; *see also* HRSA-2026-0001-2443 at 4 (Santa Ynez Valley Cottage Hospital, a rural critical access hospital in Solvang, California, stated that "as invoices

from wholesalers must be paid within 7 calendar days, even in a best case scenario where rebates are received within 10 days, the Hospital would still be floating the manufacturer for 3 days").[3]

95. *Second*, commenters noted that drugs may sit on shelves for long periods of time, further inhibiting immediate reimbursement. Commenters explained that "the requirement to maintain clinical safety stock for emergent cases necessitates that certain medications remain on our shelves longer than the pilot suggests," during which the hospital carries the full WAC cost of undispensed inventory. AHA Letter at 22. Hospitals therefore order drugs in advance, considering variable patient volumes and irregular utilization at rural hospitals. *See* HRSA-2026-0001-1843 at 1, 3 (West Virginia United Health System explaining that, given its service to "a large population of rural, low-income patients," medications "may sit on a shelf for weeks or months before being dispensed"). As one organization explained, "After purchasing a rebate drug, that drug would sit in the hospital's inventory until it is dispensed or administered to a patient (which could take weeks or months). Only then could the hospital prepare to submit its rebate claim to a manufacturer to be paid." HRSA-2026-0001-2437 at 7. University of Rochester Medicine, a New York academic health system, explained that "the cash flow impact is significantly exacerbated by the time between drug purchase and actual use, particularly for expensive, slow-moving inventory." HRSA-2026-0001-2287 at 5.

96. *Third*, commenters explained that claims often cannot be realistically submitted for 30–45 days due to administrative burdens of submitting such claims, and the 10-day rebate clock

[3] *See also* HRSA-2026-0001-0653 at 8 (Samaritan Healthcare, a rural hospital in Moses Lake, Washington, noting that it is required to pay its wholesaler "within 7 days of receiving the invoice/product for the 25 drugs"); HRSA-2026-0001-1612 at 9 (Ohio-based Nationwide Children's Hospital, explaining it pays its "primary wholesaler based on a 7-day payment term"); HRSA-2026-0001-2102 at 3 (MetroHealth, a Cleveland-based safety-net hospital, explaining it "currently operates under net seven (7) day payment terms with its wholesale drug supplier") (emphasis removed); HRSA-2026-0001-1609 at 2–3 (Keck Medicine of University of Southern California, noting that "[o]ur organization's payment terms are currently 7 days"); HRSA-2026-0001-1886 at 9 (University of Iowa Health Care, noting its wholesaler requires payment within 7 days).

only begins when a drug company receives a completed claim submission. One survey conducted by the Greater New York Hospital Association found that "30% of the survey respondents estimate that it takes 15-30 days on average from the time they acquire a drug to when a rebate claim would be submitted," that 50% estimated "31–60 days on average," and an additional "10% estimated 61–90 days." HRSA-2026-0001-2379 at 9. Individual healthcare providers from across the nation confirmed these results. *See, e.g.*, HRSA-2026-0001-2249 at 17 (McLeod Regional Medical Center of South Carolina explaining that medical "[c]laims take a minimum of 30 days after an encounter has been closed to be submitted but can take longer."); HRSA-2026-0001-2382 at 5 (Indiana University Health, explaining that medical claims for physician-administered drugs "may not be available for weeks or longer after the drug is administered"); HRSA-2026-0001-1966 at 5 (Cambridge Public Health Commission, a Massachusetts public safety-net health system, explaining that such medical claims "can be billed out weeks or months after the drug was dispensed").

97. *Fourth*, commenters explained that some wholesalers require covered entities to fund large "prepay" or escrow accounts in response to the increase in WAC invoice amounts—an obligation that negatively affects liquidity regardless of how quickly any rebate is paid. *See, e.g.*, AHA Letter at 19. For example, University of California Health reported that its wholesaler would require an increase in its prepay deposit of approximately $30 million *per quarter*—"an immediate . . . outlay of cash that's directly tied to the rebate model." HRSA-2026-0001-1986 at 6; *see also* HRSA-2026-0001-2158 at 4 (Community Voices for 340B commented that "For those covered entities with prepay or same day wholesaler repayment terms and less than one day cash on hand, a rebate model could force them out of business").

98. *Fifth*, commenters explained that many covered entities would not have available cash-on-hand to reliably pay these new large acquisition costs under the Rebate Program. Some would need to look to lines of credit or similar loans at rates of 7% to 12%, which, of course, would not be covered by the rebate.[4] One organization representing 340B hospitals noted that a 12% interest rate would translate to "$162.8 million in interest costs for all hospitals for the 340B rebate pilot" and "will only grow as the number of drugs in the [R]ebate [Program] continues to grow." HRSA-2026-0001-1994 at 16 (comment of America's Essential Hospitals). Many commenters echoed the view expressed by Self Regional Healthcare, a nonprofit regional hospital in Greenwood, South Carolina, that borrowing to fund drug procurement "fundamentally defeats the purpose of the 340B program" by "diverting patient-care funds toward interest payments, origination fees, and debt service." HRSA-2026-0001-1495 at 6; *see also* HRSA-2026-0001-1740 at 11 (Eastern Iowa Health Center, noting that "[f]orcing CHCs into debt to maintain their drug supply creates an environment of clinical instability").

99. *Sixth*, many commenters explained that the Medicare maximum fair price ("MFP") refund process, which took effect January 1, 2026, and involves some of the same manufacturers, drugs, and vendor platforms, is experiencing significant delays. That MFP program requires

[4] *See, e.g.*, HRSA-2026-0001-2383 at 11 (Jericho Road Community Health Center, a federally qualified health center in Buffalo, New York, noting that interest rates would be approximately 7.75%); HRSA-2026-0001-1520 at 9 (Flathead Community Health Center, a federally qualified health center in Kalispell, Montana, quoted interest rates of 7.75%–11%); HRSA-2026-0001-2446 at 6 (Colorado Community Health Network, the statewide association for Federally Qualified Health Centers, noting that Small Business Administration loans carry annual interest rates upwards of 12.5% and that wholesalers charge 18% interest on late balances). One comment submitted on behalf of a health center serving homeless patients told HRSA that the Rebate Program was forcing it into "possibly having to secure a line of credit or loan to finance drug inventory, absorbing interest expenses." HRSA-2026-0001-0059. The Tennessee Primary Care Association said its members' "financial strains . . . are well known, so any creditor willing to lend to them will charge above-average rates, and many may seek to put liens on CHCs' buildings." HRSA-2026-0001-1705 at 3. Of course, this is only true for the entities that can obtain credit. Some commenters explained that credit would not be available to them. *E.g.*, HRSA-2026-0001-2052 at 2 (Jefferson Comprehensive Care System, Inc. explained that it "does not maintain unfunded liquidity at that scale, and no community bank in our service area will extend a line of credit against the promise of manufacturer reimbursement on disputed rebate claims").

repayment within 14 days. CMS, Medicare Drug Price Negotiation Program: Final Guidance § 40.4.2.1 at 206. But commenters reported that payment can take thirty to forty-five days or longer. *See* AHA Letter at 21–23 & nn.27–28. Kootenai Health, a community-owned hospital in Coeur d'Alene, Idaho, explained that it had advanced roughly $5.2 million for two to three months and collected rebates on only about 25% of eligible drugs. HRSA-2026-0001-1509 at 3. Colquitt Regional Health System, a rural nonprofit hospital in Moultrie, Georgia, reported that only 45% of its qualifying MFP dispenses were processed correctly. HRSA-2026-0001-1727 at 2. Vanderbilt Health reported a 30% claim-matching error rate, HRSA-2026-0001-1593 at 3, and Cone Health, a nonprofit health system in Greensboro, North Carolina, identified an error rate of "over 50%," HRSA-2026-0001-2336 at 5. Commenters noted that the MFP experience shows that HRSA should assume some leakage of statutorily owed discounts due to incorrect delays and denials.

100. **Costs from Loss of Liquidity:** Commenters also explained that the liquid assets that safety-net facilities would need to "float" to drug companies are not otherwise idle—they are the same cash-on-hand that funds payroll, vendor payments, capital projects, and patient care. As such, every dollar floated to a manufacturer is a dollar withdrawn from another critical need.

a. Electra Memorial Hospital, a provider in rural Texas, reported that it "currently operate[s] with only 40 days cash on hand," and that "[p]aying full price for drugs and waiting for the rebate would lower that to only 20 days, risking our ability to make payroll and meet other obligatory timelines." HRSA-2026-0001-0100 at 6. The hospital added that "[r]eplacement of radios and purchase of a ventilator for our EMS service along with purchase of new monitors for the emergency room and inpatient services have all been paused in anticipation of this drain on cash flow." *Id.*

b. Samaritan Medical Center, a nonprofit community hospital in Watertown, New York, which employs nearly 2,500 people and serves a military community of 20,000, warned that "[s]ignificant cash flow constraints could impact payroll stability and place us at risk of violating debt covenants requiring 40 days cash on hand," with "serious financial consequences, including risk to ongoing operations." HRSA-2026-0001-1614 at 4.

c. Smaller providers described the same arithmetic in starker terms. Conway Regional Health System, a nonprofit health system in Arkansas, estimated that up to $600,000 in days of cash-on-hand could be tied up, emphasizing that these estimates "represent real money that could have funded capital improvements to our facilities, maintained staffing levels in critical service lines, or expanded programs serving our most vulnerable patients. Every dollar we spend financing manufacturer drug costs under a rebate model is a dollar our community loses." HRSA-2026-0001-1615 at 2. Likewise, Central Florida Health Care, a federally qualified health center serving central Florida, calculated a "[m]onthly cash-flow deficit" of approximately $1,448,307.90, which "exceeds available reserves ***and jeopardizes the health center's ability to maintain operations***." HRSA-2026-0001-1708 at 3 (emphasis added).

101. Many commenters noted that reducing cash-on-hand would also place safety-net facilities in violation of their existing bond covenants. *See* AHA Letter at 26–27. For example, Lexington Regional Health, a rural critical access hospital in Lexington, Nebraska, reported that a revolving float of just $150,000 to $300,000 would place it "at genuine risk of a technical default on debt instruments that were issued to finance the very infrastructure we use to serve our

community." HRSA-2026-0001-1573 at 2. Boston Medical Center Health System, the largest safety-net hospital system in New England, explained that "[e]ven with perfect 10-day payment terms, we lack sufficient cash reserves to finance upfront drug purchases while awaiting rebates without depleting our days of cash-on-hand below covenant thresholds." HRSA-2026-0001-2406 at 7–8; *see also* HRSA-2026-0001-1662 at 3 (Orlando Health, a nonprofit health system in Orlando, Florida, explaining that bond covenants necessitate a minimum amount of cash-on-hand and "[r]equiring our facility to float this money . . . harms our bond rating and our ability to acquire future capital").

102. Commenters also flagged other knock-on effects of delayed payments via a rebate mechanism. For example, because states require covered entities to bill Medicaid at actual acquisition cost, hospitals must wait for the rebate before they can bill Medicaid, delaying Medicaid reimbursement on top of the rebate delay itself. HRSA-2026-0001-1914 at 12–13. California's response to the enjoined 2025 Rebate Program bore out the concern. Its Medicaid agency issued guidance requiring pharmacies to delay Medi-Cal billing until *after* manufacturer rebate reconciliation, converting a single prescription into a five-step, multi-system exercise in which the covered entity must carry the full WAC cost through dispensing, data submission, rebate receipt, retroactive Medi-Cal billing, and final reconciliation. HRSA-2026-0001-1669 at 3–4 (Elica Health Centers, a federally qualified health center in Northern California).

103. Comments about the adverse cash-flow impact for safety-net providers in Maine were especially dire. The Maine Hospital Association explained that the median days cash-on-hand for Maine hospitals is down to 9.3 days from 10.6 last year, and that "[e]ven if drug companies paid within a 10-day period as required under the prior iteration of the Rebate Program, that delayed discount will have meaningful impact on our member hospitals and the patients they

serve. . . . [T]here is a high likelihood that such a rebate model would put some hospitals at risk of violating their bond covenants." HRSA-2026-0001-1530 at 3. Other Maine commenters echoed these risks.

a. One of the Maine Hospital Association's members, MaineHealth, explained that "[c]ash on hand at MaineHealth hospitals supports payroll, pharmacy purchasing, emergency services, and compliance with bond covenants," so that "[e]ven short-term disruption in cash flow, particularly during winter months and seasonal population surges, would generate cascading operational risks." HRSA-2026-0001-1946 at 6.

b. The Maine Primary Care Association explained that "[s]imply requiring manufacturers to pay rebate claims within ten days does NOT protect CHCs from these cashflow strains. This 10-day turnaround addresses only one step in a multi-step financing process; other steps (e.g., waiting for drugs to be dispensed, meeting wholesaler payment deadlines) will still force CHCs to borrow substantial amounts of cash. . . . Also note that CHCs face substantial difficulty accessing credit from the private market at reasonable interest rates. Their financial strains (including the uncertainty around their federal grant funding and their low/negative margins) are well known, so any creditor willing to lend to them will charge above-average rates, and many may seek to put liens on CHCs' buildings." HRSA-2026-0001-1702 at 2–3.

c. One Maine community health center, Penobscot Community Health Care, explained that it was "particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead them to exceed their

> credit limits with wholesalers, halting their ability to order medications until payments are submitted." HRSA-2026-0001-1991 at 9 (emphasis removed). It further noted that "the risk of our credit limit being reached or our reserves being depleted is a direct threat to the community's safety net. If we are forced into financial limbo, the 'trickle-down' effect is immediate: longer wait times, reduced service availability, and a weakened ability to provide the steeply discounted medications that our 52 million patients across the country depend on." *Id*. at 13.

104. **Lost Prompt-Pay and Cost-of-Goods-Sold Discounts**: Commenters also identified costs that can never be recouped by rebates. As many explained, a rebate mechanism forces covered entities to forever forfeit the cost-of-goods-sold ("COGS") and prompt-pay discounts negotiated with wholesalers—generally 3% to 10% of a drug's cost—that are already built into their pharmacy budgets. *See* AHA Letter at 25. West Virginia United Health System, for example, noted that "[o]ver the course of one year, we estimate our hospital will be forced to forgo annual pre-pay discounts of $3.2 million dollars." HRSA-2026-0001-1843 at 3 (emphasis removed). Likewise, Regions Hospital, a nonprofit safety-net teaching hospital in St. Paul, Minnesota, reported it "would lose $2 million in prompt pay discounts per year" under the Rebate Program. HRSA-2026-0001-2030 at 12; *see also* HRSA-2026-0001-1839 at 2 (Bayhealth Medical Center, explaining the Rebate Program would forfeit "our prompt payment refunds"); HRSA-2026-0001-1664 at 3 (Saint Catherine Hospital, explaining that the Rebate Program could lead them to "forgo early payment discounts to preserve cash flow, but doing so would cost our organization a significant amount of money").

105. Other providers told a similar story. Fresno Community Hospital and Medical Center, a nonprofit safety-net health system in California's Central Valley, estimated that loss of these discounts alone would increase its acquisition costs for the pilot drugs by 9.5%. HRSA-2026-0001-1479 at 2. The University of Texas Medical Branch, an academic medical center in Galveston, Texas, estimated approximately $9 million annually. HRSA-2026-0001-1532 at 6. Nationwide Children's Hospital explained that these forgone discounts "would be a permanent loss not recuperated from the manufacturer 340B rebate program." HRSA-2026-0001-1612 at 8.[5] And the Maine Primary Care Association's comment letter listed the following as "Direct Financial Losses" from a rebate mechanism:

a. Loss of sub-ceiling discounts on pilot drugs (estimated at 10% - 15% of 340B price).
b. Loss of prompt payment discounts on all drug purchases (not just rebate drugs), which range from 1% to 5% of 340B purchase price.
c. Loss of other discounts, including volume discounts and Cost of Goods Sold discounts.

HRSA-2026-0001-1702 at 9. None of these losses would be recoverable through rebates.

Non-Economic Costs to Healthcare Services and Patient Care

106. Commenters explained that every dollar of administrative and float costs would have downstream effects on patient care. They catalogued the many ways in which reduced care and operations would result in patient harm. As Glacial Ridge Health System put it, the cuts resulting from Rebate Program costs "are not minor inconveniences—they are meaningful reductions in access to care." HRSA-2026-0001-1503 at 3.

107. **Reduced Drug Discounts for Low-Income Patients:** Many covered entities use 340B savings to provide drugs to patients for free or far below cost through patient assistance

[5] In addition, some states tax drug purchases at the higher WAC price. For example, Lakewood Health System, a 25-bed critical access hospital in Minnesota, explained that a 1.8% state tax would apply to the full WAC price. HRSA-2026-0001-1382 at 2.

programs and sliding-fee scales. For example, Hannibal Regional Healthcare System, a Missouri rural health system, explained the Rebate Program would reduce its 340B net benefit on the pilot drugs by an estimated 20–25%, and that money "is currently used to subsidize our sliding-fee scale for uninsured patients." HRSA-2026-0001-1554 at 2.

108. Other commenters warned that a Rebate Program would force them to curtail or terminate those vital patient-assistance programs. Graham County Hospital warned "[w]e will likely shut down our patient assistance program." HRSA-2026-0001-0048 at 4. Mosaic Health System, a nonprofit rural health system based in Missouri, likewise noted the Rebate Program would "reduce or eliminate patient assistance programs designated to the uninsured and under insured patient populations[.]" HRSA-2026-0001-1849 at 2. Other commenters flagged similar patient assistance programs imperiled by the Rebate Program. *See, e.g.*, HRSA-2026-0001-2109 at 5 (Wellstar Health System, Inc., a nonprofit health system in Georgia, noting the Rebate Program would lead to "scaling back or elimination" of medication-assistance programs); HRSA-2026-0001-0058 at 4 (Bitterroot Health Daly Hospital, noting its "SunRx cash-card program" would be imperiled). This burden reached Maine, with MaineHealth warning that "[f]or MaineHealth's hospitals . . . erosion of 340B savings would require reassessment of . . . the provision of free or discounted drugs to uninsured patients." HRSA-2026-0001-1946 at 5.

109. **Reduced Medication Inventory and Access**: Hospitals that lack the cash to acquire high-cost drugs at WAC explained that they will be forced to carry minimal inventory (or none at all). *E.g.*, AHA Letter at 30. Electra Memorial Hospital warned it would be forced "to remove high-cost drugs from our stock," likely "result[ing] in hospitalizations." HRSA-2026-0001-0100 at 7. University Medical Center El Paso warned that access to "[h]igh-cost drugs for specialty services like rheumatology, infectious disease, dermatology, and neurology could be

negatively impacted." HRSA-2026-0001-1514 at 3; *see also* HRSA-2026-0001-1445 at 3 (Cozad Community Hospital, a rural critical access hospital in Nebraska, noting that "[a] rebate model could also affect our ability to stock certain high-cost medications," and could force them to "reconsider stocking some therapies due to financial risk"). As the American Pharmacists Association explained, "some members working with high-cost specialty medications expressed concern that their organizations may reduce their specialty drug formularies or discontinue stocking certain high-cost 340B-eligible drugs due to the high carrying costs, thereby decreasing patient access to these medications." HRSA-2026-0001-1797 at 4.

110. Commenters also warned that the Rebate Program could disrupt contract pharmacy arrangements. In November and December 2025, for example, Walmart and Walgreens announced that they would not provide 340B pricing for the ten drugs in the original Rebate Program, and Walmart excluded all MFP drugs dispensed under Medicare Part D from covered entities' pharmacy services agreements, citing the "new reimbursement mechanism" and "operational constraints." AHA Letter at 32 & n.33. When those relationships lapse, patients—particularly rural patients—must travel long distances for medications they could previously fill nearby. *Id.*

111. **Reduced Patient Services:** Commenters detailed the specific services that even a limited Rebate Program would place at risk. For example, CaroMont Regional Medical Center, a nonprofit hospital in Gastonia, North Carolina, warned that the Rebate Program's costs risked forcing it to close its labor-and-delivery unit and its 63 licensed inpatient behavioral-health beds—the only such services in its county. HRSA-2026-0001-1643 at 4. Woman's Hospital, a nonprofit women's specialty hospital in Baton Rouge, Louisiana, identified mobile mammography, perinatal mental-health services, and HIV post-exposure prophylaxis as programs sustained by 340B savings. HRSA-2026-0001-1408 at 5. The Iroquois Healthcare Association explained that the costs

would "translate[] directly into program cuts, service line reductions, ***and in some cases potential facility closures***." HRSA-2026-0001-0023 at 3 (emphasis added); *see also* HRSA-2026-0001-1504 at 4 (Los Angeles County Department of Public Health, noting the Rebate Program would "reduc[e] the ability to respond to communicable disease outbreaks"); HRSA-2026-0001-1644 at 8 (Johns Hopkins Health System, warning about the erosion of $412 million in annual community benefit activity).

112. The consequences would be most acute in rural communities, where replacement services may be hours away. Heart of America Medical Center in Rugby, North Dakota, explained that patients would have to travel at least 60 miles to replace its cardiac-rehabilitation and diabetes-education programs. HRSA-2026-0001-0037 at 3. Community Care of West Virginia, a federally qualified health center serving rural West Virginia, reported that its essential services are "at risk of elimination." HRSA-2026-0001-1610 at 3. Morris County Hospital warned that losing "up to 20% more from delayed or denied rebate dispenses would likely force [it] to close some services," including "[o]bstetrics and/or pulmonary rehab." HRSA-2026-0001-1435 at 5; *see also* AHA Letter App. B (collecting comments).

113. **Disparate Localized Impact on Communities:** Many comments described how a Rebate Program would have a particularly negative impact on certain rural and underserved communities, imposing an outsized burden on specific populations. For example:

a. Many commenters flagged that rural communities served by 340B hospitals would be particularly harmed by the Rebate Program, because, for example, the unavailability of drugs at local facilities would force patients to drive great distances to the next facility that had them in stock. Lincoln County Medical Center noted that "[i]n rural communities, reductions in hospital services do not

result in inconvenience; they result in patients traveling long distances or foregoing care altogether." HRSA-2026-0001-2048 at 2; *see also* HRSA-2026-0001-2451 at 4 (comment from Shoshone Medical Center in Kellogg, Idaho, warning that the Rebate Program risks cutting staffing and services, and that "[t]he next closes[t] hospital is 38.6 miles away"). The Kansas Hospital Association added that "a rebate model could result in more rural hospital closures." HRSA-2026-0001-1424 at 2; *see also* HRSA-2026-0001-1689 at 10 (comment from Clinicas De Salud Del Pueblo warning that they will need to cut clinic hours and "for our most rural sites where we are the only provider we may need to limit days we are open or close the site entirely").

b. Many other commenters flagged that tribal communities would be acutely harmed by the Rebate Program and the costs associated with it. The Oneida Nation wrote that "Tribal healthcare facilities rely on the immediacy of 340B savings to support pharmacy operations, maintain cash flow stability, and sustain access to essential and high-cost medications for patients." HRSA-2026-0001-1698 at 2. The Pascua Yaqui Tribe noted that "[a]ny delay in realizing these savings would create cash flow gaps that could force us to reduce pharmacy hours, defer drug purchases, or draw from other program funds needed to support direct patient services." HRSA-2026-0001-1607 at 2; *see also* HRSA-2026-0001-2221 at 2 (comments of Northwest Portland Area Indian Health Board that "[t]he requirement to pay the full cost at the time of purchase will cripple the ability of IHCPs [Indian Health Care Providers] to provide healthcare services to their communities").

c. Several covered entities in Maine and their representative organizations described particular harms that would befall Maine communities under the Rebate Program. These commenters noted, for example, that many of the contract pharmacies with whom they work would likely drop out of the 340B Program for the drugs covered in the Rebate Program, as these pharmacies had announced they would in the lead-up to the first proposed Rebate Program. HealthReach Community Health Centers, operating in 12 Maine towns and serving 26,740 patients, warned that "[w]e already experienced this prospect [of lost pharmacy partners] in early 2026, when several of our contract pharmacies eliminated the 2026 MDPNP selected medications from the 340b program." HRSA-2026-0001-2187 at 1, 4. In practice, this would mean a lack of affordable medication options in different Maine communities. *See, e.g.*, HRSA-2026-0001-1702 at 3–4 (comment of Maine Primary Care Association); HRSA-2026-0001-1946 at 5 (comment of MaineHealth).

114. **Timing/Financial Environment**: Commenters separately explained why imposing these burdens in 2026 and 2027 would be especially damaging. They explained, among other things, that hospital expenses are rising roughly 5% year over year; bad debt and charity care are up 8%; drug expenses are up 7%; and the OBBBA is projected to reduce hospital revenues by $68 billion over those two years, falling most heavily on 340B hospitals. AHA Letter at 35–38; HRSA-2026-0001-1914 at 8 (citing OBBBA's "historic $1 trillion cut" from Medicaid and Marketplace spending). Individual providers described the combination of OBBBA cuts—including $137 billion in cuts to rural hospitals over ten years—and manufacturer contract-pharmacy restrictions as a "perfect storm." HRSA-2026-0001-1382 at 3 (Lakewood Health System); HRSA-2026-0001-

1534 at 2 (Astera Health); *see also* HRSA-2026-0001-1399 at 9 (Valleywise Health, a public safety-net health system in Phoenix, Arizona, noting the need for cash reserves against "OBBBA-related impacts" "is not discretionary").

115. All in all, the record before Defendants thus went well beyond generalized apprehension. Commenters supplied *specific* dollar figures, *specific* staffing plans, *specific* categories of discounts (*e.g.*, COGS and prompt-pay discounts) that they will forgo entirely, *specific* wholesaler contract terms requiring payment in less than 10 days, *specific* financing costs, *specific* liquidity challenges, *specific* bond-covenant thresholds, and four or more months of *specific*, documented operating experience under the analogous MFP rebate mechanism. They also identified the *specific* consequences those costs would have for individual facilities and their patients, and they *specifically* explained why imposing these costs in 2026 and 2027 would be particularly damaging. The Notice engages with almost none of this evidence.

Obvious and Less Burdensome Alternatives to a Rebate Program

116. Commenters proposed several alternatives to the Rebate Program that would address the underlying concerns that HRSA flagged in its RFI and elsewhere.

117. **Prospective Discounts and a Data Clearinghouse**: Commenters explained that concerns regarding duplicate discounts could be addressed by less costly and less disruptive mechanisms. The AHA, for example, proposed that drug companies could prospectively publish both the 340B price and the MFP, and covered entities could then maintain two wholesaler accounts and replenish at the lower of the two prices. AHA Letter at 47.

118. Others explained that CMS could require *prospective* effectuation of the MFP at the point of sale, so that non-340B pharmacies purchase at the MFP while covered entities continue to receive the 340B discount upfront. In the rare case where the MFP is lower than the 340B price,

the covered entity would submit limited data to the existing Medicare Transaction Facilitator ("MTF")—the federal clearinghouse CMS already operates to route claims data to manufacturers and payments back to dispensing entities—which would credit the difference. Doing so would "negate the need for retrospective 340B rebates" entirely. HRSA-2026-0001-1914 at 5–6 (comment of AAMC).

119. To the extent HRSA believed data-sharing was necessary to ensure deduplication, commenters identified an obvious alternative to handing hospitals' claims data to drug manufacturers and their agents: using a neutral clearinghouse—operated by HRSA itself or by a conflict-free, government-contracted vendor—that would verify pricing and facilitate any reconciliation without a rebate. AHA Letter at 47–48 & n.49. The National Association of Chain Drug Stores, for example, proposed "[t]he agencies should consider the development of a centralized clearinghouse run by a conflict-free vendor," noting that "CMS has already stated it plans to develop and test such a model." HRSA-2026-0001-0042 at 2. The national pharmacy chain, Walgreens, agreed, explaining "[t]his approach is not without precedent" because "CMS has already proposed testing a clearinghouse-like model that the agency is calling a '340B repository.'" HRSA-2026-0001-1548 at 3. Commenters pointed to existing federal infrastructure that could do the job—the MTF and the Medicare Part D Claims Data 340B Repository that CMS established to identify Part D prescriptions dispensed under the 340B Program. AHA Letter at 47–48 & n.49; HRSA-2026-0001-1914 at 6. Either option would avoid foisting massive costs on covered entities.

120. **Existing Accountability Mechanisms Are Sufficient:** Commenters also reminded HRSA of Defendants' own admissions that a rebate mechanism is unnecessary for deduplication. Defendants told the First Circuit on December 30, 2025, that "[m]anufacturers have alternate

means to deduplicate discounts," and said the same to the D.C. Circuit on December 31, 2025, and February 10, 2026. AHA Letter at 40. Commenters also catalogued the mechanisms that already identify and prevent duplicate discounts, such as the Medicaid Exclusion File, state billing modifiers, HRSA's annual audits, manufacturer audits on reasonable cause, and statutory sanctions and removal—tools that assign oversight to HHS rather than to drug companies conducting their own opaque enforcement. HRSA-2026-0001-1914 at 13–18 (comment of AAMC); AHA Letter at 42–46.

121. **A True "Pilot":** Finally, commenters explained that even a genuine desire to "test" a rebate mechanism does not require a mandatory, nationwide program that includes covered entities of all kinds, sizes, and locations. The AHA proposed "a volunteer-only program that would allow covered entities to opt-in," urged HRSA to solicit volunteers before declaring a voluntary design unworkable, and identified an obvious way to fill the pool—"by requiring drug companies to cover *all* costs for those volunteers. If the drug companies believe that a rebate mechanism will pass HRSA's 'test,' then they should be eager to put their money where their mouths are." AHA Letter at 47; *see also* HRSA-2026-0001-1914 at 11 (AAMC comment, to same effect). Commenters also proposed narrowing any pilot to a defined subset of drugs, limiting it by covered-entity type, and phasing it in. *See, e.g.*, HRSA-2026-0001-0721 at 3–4 (Erlanger Health System in Hamilton County, Tennessee); HRSA-2026-0001-2382 at 10 (Indiana University Health); HRSA-2026-0001-2225 at 4 (Rural Wisconsin Health Cooperative in Sauk City, Wisconsin); HRSA-2026-0001-2319 at 6 (Pillr Health, a 340B TPA).

Rejecting HRSA's Balancing Approach/Choosing the Most Effective and Most Efficient Payment Mechanism from the Standpoint of the Covered Entities

122. Finally, in response to HRSA's comment in its RFI about "balancing" interests of drug companies against those of the covered entities, many commenters explained why this

balancing approach was wrong under the statute. Commenters specifically quoted the "standpoint" standard throughout the administrative record. *See, e.g.*, HRSA-2026-0001-1628 at 2 (Sun River Health, quoting "standpoint" standard from Committee Report); HRSA-2026-0001-2011 at 17–18 (HopeHealth, to same effect); HRSA-2026-0001-2268 at 24 (Wright Centers for Community Health and Graduate Medical Education, to same effect); HRSA-2026-0001-1929 at 13 (Colorado Coalition for the Homeless, to same effect). As AHA explained, HRSA "must give primacy to covered entities on this issue" under H.R. Rep. No. 102-384, pt. 2, at 16, and its "balance-the-interests-of-two-industries" approach is "the wrong lens through which to view this question." AHA Letter at 2–3, 7 (emphasis removed); *see also* HRSA-2026-0001-1965 at 21 (similar comment from National Association of Community Health Centers).

HRSA Ignored Additional Evidence About the True Labor Costs of a Rebate Program in June 2026 ICR

123. The 2,400-plus comments submitted in response to the RFI demonstrated that HRSA's first estimate of the program's burden—3.8 million hours of labor—was nowhere near the proposed Rebate Program's real cost. Yet HRSA ignored those comments and refused to budge from the initial cost estimates that it had calculated prior to even receiving comments.

124. On June 15, 2026, HRSA submitted its ICR to the Office of Information and Regulatory Affairs ("OIRA") and published a second notice raising the covered-entity population to 15,249 and the annual burden to 3,964,740 hours. Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, 91 Fed. Reg. 35,989, 35,991 (June 15, 2026) ("June ICR"); *see* OIRA Reference No. 202606-0906-001. HRSA updated the entity count but left its 5-hour-per-week assumption in place. 91 Fed. Reg. at 35,990–91. The agency priced the program's burden on covered entities at $523,345,680 per year, disregarding the

real-world data supplied over prior months showing a much higher price tag. ICR Supporting Statement at 11; *see* Notice, 91 Fed. Reg. at 48,893 & n.20.

125. The June ICR contains one cursory sentence to justify the 5-hour-per-week figure underpinning the entirety of the $523 million cost estimate:

> To estimate burden, HRSA applied a task-based methodology that considers the discrete activities required to complete a reporting cycle, including: (1) identifying and extracting eligible claims data; (2) formatting and validating data to meet manufacturer specifications; (3) submitting the data; (4) reconciling submissions and tracking rebate status; and (5) addressing errors, denials, or follow-up requests.

91 Fed. Reg. at 35,990. There is no further explanation of this "task-based methodology," what inputs HRSA used, or why HRSA chose not to disclose any of that underlying information. HRSA also claimed that it "evaluated the range of estimates provided by commenters . . . and normalized these inputs into a per-response estimate consistent with PRA requirements," *id.*, but HRSA's 5-hour-per-week calculation had been developed long *before* the agency had received comments and was never altered in response to those comments. *See* February ICR, 91 Fed. Reg. at 9,632–33.

126. The June ICR commenced a new comment period ending July 15, 2026. HRSA received more than 175 additional comments in the ICR docket.[6] Numerous letters identified specific defects in HRSA's 5-hour-per-week assumption. 340B Health, a nonprofit organization representing more than 1,600 covered entities, noted that HRSA's estimate "rests on unfounded and heavily contradicted assumptions" and "significantly understates" actual costs. Ex. 1 at 108 (emphasis removed). Parkview Health, an Indiana nonprofit health system, noted HRSA's estimate is "unsupported and is internally inconsistent with HRSA's own definition of 'burden,'" and "omits the largest components of its own stated burden definition." Ex. 1 at 17–18. Allegheny Health Network added that HRSA's median "reflects an assumption that Covered Entities will

[6] The documents cited in Exhibit 1 are comments in response to HRSA's ICRs.

simply extract and submit data, which is a gross oversimplification" that "ignores the full lifecycle of a rebate process." Ex. 1 at 121 (emphasis removed). Boston Medical Center Health System put it simply: "HRSA is underestimating the covered entities[']' administrative burden[.]" Ex. 1 at 128. Titusville Area Hospital, a critical access hospital in Titusville, Pennsylvania, similarly reported that HRSA's five-hour-per-week estimate "is significantly understated and does not reflect the operational realities faced by covered entities." Ex. 1 at 7.

127. One threshold defect was that the estimate's methodology was opaque, making the estimate itself impossible to substantiate. As one health system in Utica, New York explained, HRSA's estimate "is not . . . accompanied by sufficient explanation to permit meaningful public review." Ex. 1 at 147 (Mohawk Valley Health System). HRSA did not identify the assumptions underlying its calculation, including "the volume of expected claims transactions," frequency of data submissions and reconciliation events, staff time required to resolve disputes or denials, or the costs of implementing and maintaining compliant systems. *Id.* Similarly, Plaintiff AHA explained that HRSA "must explain . . . exactly how it came to its 5-hour 'median' figure based on the actual numerical estimates in the record, rather than broad conclusory assertions" and cannot rely on a median without explaining "why [it] is the best measure in the first place." Ex. 1 at 29.

128. Other commenters identified a separate incorrect premise underlying the estimate: HRSA's assertion that rebate submissions would be "materially similar" to claims that covered entities already submit to Medicare, Medicaid, and commercial payers. Commenters explained that, while "[c]laims to Medicare, Medicaid, and commercial plans adjudicate electronically at the point of sale through the pharmacy switch," a rebate mechanism instead requires "retrospective file assembly, transmission through a third-party platform, and a waiting period" while the covered entity determines whether "the data matched, the platform functioned, and the manufacturer" will

pay. Ex. 1 at 136 (Holton Community Hospital, a critical access hospital in Holton, Kansas); *see also* Ex. 1 at 172 (Minneola Healthcare, a critical access hospital in Minneola, Kansas, explaining that "ordinary payer claims clear through a pharmacy switch in real time at point of sale," whereas "[a] rebate model does not operate in real time, rather requires covered entities to stitch data together from the disparate sources" that hold the required data). Parkview Health likewise explained that rebate submissions have "no analog in routine payer billing," because covered entities must "determine, claim by claim, whether a dispense is 340B-eligible . . . and then push that eligibility determination . . . into a manufacturer-controlled platform in order to recover a discount the entity is already entitled to by statute." Ex. 1 at 19. And 340B Health noted another commenter's observation that hospital systems "do not currently operate through a single automated data feed that can easily generate the information required to support rebate submissions." Ex. 1 at 113 (citation and emphasis omitted).

129. Commenters also noted that HRSA's estimate "assumes the automation works every time." Ex. 1 at 136. But, as the Kansas Hospital Association explained, "third party vendor automation does not always work," citing "340B ESP glitches, TPA glitches, and concerns regarding Beacon," and that HRSA's estimate fails to account for the "manual clean up and reconciliation" required when those systems fail. Ex. 1 at 141.

130. In general, moreover, commenters noted that HRSA could now rely on months of actual operating experience under the MFP process rather than predictions, and that experience did not support HRSA's assumptions. Mohawk Valley Health System reported, "We now have six months of experience working with Beacon [the same vendor proposed in 2025 to administer the Rebate Program] . . . and have experienced significant setbacks and struggles. . . . These denials have resulted in financial losses for our organization that we have been unable to resolve going

back to the inception of this program in January 2026." Ex. 1 at 147–48. It estimated that MFP compliance "currently requires approximately, at a minimum, 15 hours per week." *Id*. MultiCare Health System rejected HRSA's assumption that "rebate administration functions are largely automated" because, "[b]ased on MultiCare's direct experience administering manufacturer rebate programs, [this] assumption is [not] accurate," and reported that a single disputed claim requires "an average of 40 minutes" of manual investigation. Ex. 1 at 151, 153.

131. Others flagged real-world experiences that signaled massive costs for covered entities that HRSA had not considered. Boston Medical Center Health System reported that "[r]eal-world rebate administration data" from "[e]arly manufacturer rebate programs" showed that "[a]pproximately 10% of claims eligible for payment were incorrectly rejected," "[a]pproximately 30% experienced payment delays," and "[a]pproximately 40% of submitted claims required manual intervention or experienced processing issues." Ex. 1 at 129. National Jewish Health, a "small specialty hospital" in Denver, Colorado, explained that its "direct experience with existing rebate processes, including those associated with the Medicare Drug Price Negotiation Program," made clear that "[t]he incremental staffing and system costs associated with a rebate model are estimated at no less than $824,045 annually, excluding financing costs related to delayed cash flow. In many years, this would eliminate our entire operating margin." Ex. 1 at 167–68; *see also* Ex. 1 at 159 (Wayne Community Health Centers, which serves central Utah, drew on "real-world experience administering the Medicare Maximum Fair Price (MFP) rebate program over the past six months" to demonstrate that "each of these activities requires substantially more time than estimated").

132. Commenters' experience with the vendor that HRSA chose to administer the Rebate Program—Second Sight Solutions, which operates the Beacon platform and the related

340B ESP platform—was especially damning, but the Notice says nothing about it. AHA noted that "Second Sight Solutions cannot handle the work it already has, so we can easily expect more bugs, delays, and incorrect denials in the future." AHA Letter at 17. The Greater New York Hospital Association surveyed its members about the Beacon platform and reported that *82% experienced problems with the platform's system functionality*. HRSA-2026-0001-2379 at 8. Dartmouth Health reported that drug companies, "through their agent Second Sight Solutions, have automatically denied rebate claims within the Platform simply because the pharmacy is owned by . . . a 340B covered entity," "essentially holding the rebates 'hostage' and requiring the pharmacy to 'float' the full undiscounted acquisition cost of the drug." HRSA-2026-0001-2419 at 5. University of Rochester Medicine described receiving a notice from Second Sight warning that its hospital "may lose access to 340B pricing at its contract pharmacy," only to recant—an experience it reported is "not uncommon" and "will undoubtedly increase exponentially" under a Beacon-administered rebate model, "making HRSA's staffing estimates entirely unrealistic." HRSA-2026-0001-2287 at 6–7. Freeman-Oak Hill Health System described "[o]ften being 'timed out' of the platform while in the process of submissions," and noted "the hold time for 'chat help' has often exceed[ed] thirty (30) minutes"; in its view, the Beacon "platform is not capable of handling the volume of work." HRSA-2026-0001-1638 at 5. Beauregard Health System reported that Beacon demanded forms from when the hospital "first opened" in "the early 1950's" that "do not exist." HRSA-2026-0001-1572 at 5. St. Luke's Health System explained Second Sight's deficiency notices "are frequently vague and fail to identify what information is allegedly missing or why," forcing its compliance team "into frustrating cycles of guesswork, resubmission, and repeated follow-up." HRSA-2026-0001-2141 at 5.[7]

[7] Many other commenters described the same problems. *See, e.g.*, HRSA-2026-0001-2382 at 8 (Indiana University Health describing "shifting and inconsistent data submission requirements, problematic Terms and Conditions that

133. Commenters also provided HRSA with data and individualized experience showing that the agency's disregard of back-end reconciliation labor results in dramatically underestimated costs. For example, the National Association of Community Health Centers ("NACHC") conducted a time study of data submission and back-end reconciliation tasks, drawing on time studies and time estimates from 24 community health centers. Depending on certain variables, such as claim classification and claim denial rates, NACHC estimated that the two reconciliation tasks alone (reconciling submissions and tracking rebate status, and addressing errors, denials, and follow-up requests) would average roughly 13 to 38 hours per week. Ex. 1 at 194–96.

134. Others offered facility-level data that corroborated these larger estimates. Henry Ford Health, a nonprofit academic health system in Detroit, Michigan, estimated 10 to 20 hours per week of rebate reconciliation and dispute management alone. Ex. 1 at 183. Southwest Mississippi Regional Medical Center, a hospital in McComb, Mississippi, estimated 8 to 12 hours per week of finance staff time for rebate tracking, reconciliation, and variance analysis alone, within a total estimated burden of 29 to 45 hours per week. Ex. 1 at 186; *see also* Ex. 1 at 178 (American Society of Health-System Pharmacists noting that "[r]econciliation and claims denial management add hours of weekly burden per covered entity. . . . The time associated with these activities matches or exceeds HRSA's entire burden estimate"). Commenters also identified important developments that post-dated the April comments. On July 14, 2026, CMS proposed in its calendar year 2027 Physician Fee Schedule rule to require only seven data elements to identify and exclude 340B claims from Medicare Part D, compared with the eleven or more HRSA would

raised significant data privacy and security concerns, and inadequate customer service"); HRSA-2026-0001-1627 at 4 (Trinity Health reporting that Beacon's "build was continuously changing and was a 'work in progress' even as the pilot was about to begin"); HRSA-2026-0001-2386 at 9 (Baptist Health South Florida reporting that Beacon claim approvals "routinely consume the full 14-day window, or longer, despite available data, which would critically delay fund access under a rebate model"); HRSA-2026-0001-1517 at 12 (NASTAD explaining that Second Sight's 340B ESP platform "caused extreme processing delays" lasting "frequently 12 weeks or more despite promised 10-business-day turnarounds").

demand, *see* 91 Fed. Reg. at 48,903, leading a commenter to observe that "it would be highly irregular for [CMS's] sister agency to require Covered Entities to disclose more or different data to a private, for-profit data aggregator." Ex. 1 at 148 (Mohawk Valley Health System); *see also* Ex. 1 at 209 (Beth Israel Lahey Health, a Massachusetts health system, to same effect); Ex. 1 at 214 (University of Arkansas for Medical Sciences, same); Ex. 1 at 220 (Pikeville Medical Center, Inc., a hospital in eastern Kentucky, same).

HRSA Announces the Same Rebate Program as Before, Just 2.5 Times Larger and With No Clear End Date

135. Just nineteen days after the June ICR comment period closed, Defendants published the Notice without responding to any of the ICR comments. On August 3, 2026, HRSA published the Notice, announcing "the availability of a revised 340B Rebate Model Pilot Program," effective immediately. 91 Fed. Reg. at 48,883. The Rebate Program's overarching structure is identical to the program this Court enjoined in December 2025. Covered entities are required to purchase covered drugs at WAC through their existing wholesaler accounts, submit claims-level data to manufacturers through manufacturer-selected IT platforms, and await a rebate calculated as WAC minus the 340B ceiling price on the day of dispense. *Id.* at 48,902–03.

136. The meaningful differences between this Rebate Program and the one this Court enjoined all run in one direction: more cost for safety-net providers. HRSA increased the eligible drugs from 10 to 25, all of which were selected from "among the 50 qualifying single source drugs with the highest [Medicare] total expenditures" over the previous twelve months. 42 U.S.C. § 1320f-1(d)(1)(A); *see id.* § 1320f-1(a)(1)–(2), (b)(2); 91 Fed. Reg. at 48,901–02. HRSA raised the number of eligible manufacturers from 10 to 13 and made participation mandatory for every covered entity in the country (roughly 650 more than the year before) while keeping the Program voluntary for manufacturers. 91 Fed. Reg. at 48,893, 48,900 n.32. This so-called "pilot" also has

no time limit. HRSA described this version as covering its "first year," does not commit to publishing its first evaluation until sixteen months after the Program begins, *id.* at 48,901, and sets no end date. *See id*. at 48,902 (plans run "for a minimum 1-year period").

137. HRSA claimed it "carefully reviewed and evaluated all comments," "conducted a systematic assessment of stakeholder input," and "considered both the substance and the evidentiary support of the comments received." *Id.* at 48,888. But the Notice belies those claims. HRSA's treatment of the cost evidence followed a repeating pattern. It vaguely acknowledged some covered entities' estimates, declared without analysis that they "rest on assumptions that do not align with the design of the Pilot," and dismissed them on a conclusory ground. *See, e.g.*, *id.* at 48,893. Meanwhile, HRSA consistently adopted the assertions of drug companies and their technology vendors as fact, without ever critically examining their lack of firsthand experience, basis for knowledge, or self-interest. *Id.* at 48,891, 48,893. HRSA also rejected obvious, less burdensome alternatives on conclusory, speculative, circular, or other illogical grounds. And it never offered an explanation about how the Rebate Program and the accompanying hundreds of millions of dollars in costs are the "most effective and most efficient" mechanism "from the standpoint of each type of 'covered entity'"—which they could not possibly be. *See id.* at 48,885 (quoting H.R. Rep. No. 102-384, pt. 2, at 16 (1992)).

HRSA Failed to Quantify Any Specific Benefit of a Rebate Program and Provided No Actual Remedy for Suspected Medicaid Duplicate Discounts

138. Prevention of duplicate discounts is the principal justification HRSA has offered for departing from more than thirty years of precedent and imposing, at minimum, more than half a billion dollars in annual costs on covered entities. *Id.* at 48,887. Yet HRSA has never attempted to quantify the amount of duplicate discounts (despite commenters pressing it to do so) or proven that duplicate discounts are a significant problem. The Notice even concedes that "there is no

federal estimate of the financial extent of duplicate discounts in 340B," *id*., and the only figures the Notice cites are the drug industry's.

139. The Notice says that "[m]anufacturer commenters stated in 2019, when the 340B program was less than half its current size," that Medicaid/340B duplicate discounts "amounted to as much as $1.5 billion annually." *Id.* HRSA offered no independent verification of this figure and did not interrogate the veracity of the number, despite acknowledging the figure came from the very drug companies that will profit from a rebate mechanism.[8] The Notice later asserts that "industry analyses" suggest duplicate discounts "may affect up to approximately 25% of 340B drug transactions, representing tens of billions of dollars annually," *id.* at 48,898, again attributed only to unnamed "commenters." HRSA quoted this number unquestioningly, did not note its speculative nature ("may affect"), and did not interrogate its accuracy or methodology. In fact, HRSA described the number in more neutral terms about "industry analyses," cloaking the fact that this 25% number comes directly from drug company comment letters. *See, e.g.*, HRSA-2026-0001-2220 at 3 (UCB, Inc., a global biopharmaceutical company, writing that "[a]ccording to one estimate, approximately 25% of 340B sales represent a duplicate discount"). Importantly, nowhere does the Notice acknowledge that the Rebate Program covers but a fraction of 340B drug sales—HRSA estimated that all 25 eligible drugs would only be 5.5% of total 340B drugs, 91 Fed. Reg. at 48,893—and would therefore yield but a fraction of recovered duplication costs under the best of circumstances.

[8] The drug company comment letters citing this $1.5 billion figure did not hide their self-interested source: a 2021 annual report by Kalderos, one of the vendors that has promoted a rebate mechanism and stands to benefit greatly from it. HRSA-2026-0001-2226 at 5 (J&J); HRSA-2026-0001-1667 at 4 (GSK); HRSA-2026-0001-1895 at 6, 9 (PhRMA).

140. In its uncritical adoption of these numbers, HRSA studiously ignored comments showing, based on both HHS's audits and covered entities' own audit findings, that duplicate discounts occur much less frequently than drug manufacturers assert and have declined over time. For example, the AHA explained that HRSA's own audit data shows that duplicate discounts at 340B hospitals have plummeted since 2018. *See* AHA Comment Letter on Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14998), at 8–12 (Aug. 27, 2025), cited in AHA Letter at 42 n.47 and incorporated by reference, *id.* at 1 n.1. As one organization representing covered entities explained, HRSA "applies that [duplicate discount] label [to] data-entry errors, not actual findings of duplicate discounts. HRSA does not determine whether such data entry errors actually resulted in manufacturers paying a rebate on 340B Medicaid claims. In fact, HRSA's routine audits of CEs demonstrate that 340B compliance and integrity is high, including data pertaining to fee-for-service (FFS) Medicaid claims." HRSA-2026-0001-2437 at 13 (comment of 340B Health); *see also* HRSA-2026-0001-2105 at 11 (comment from Henry Ford Health that "recent HRSA audits, including those conducted at Henry Ford Health, have consistently demonstrated that diversion and duplicate discounts are not widespread areas of noncompliance, confirming that the current model already protects program integrity").

141. Likewise, HRSA ignored comments from numerous hospitals reminding the agency that it did not identify duplicate discounts during HRSA's own audits of their facilities. For example, Corewell Health, a Michigan nonprofit health system, reported that "[w]e have never had duplicate discount findings in our audits," with all entities audited, some multiple times, and duplicate discount and diversion audits conducted monthly and annually. HRSA-2026-0001-2018 at 6. Henry Ford Health reported "clean audit records across all manufacturer and HRSA audits for at least the past 10 years." HRSA-2026-0001-2105 at 10. Community Memorial Hospital, a

12-bed nonprofit rural hospital in Sumner, Iowa, reported that quarterly external audits over the prior year "have shown duplicate discount transaction rates ranging from 0% to a maximum of only 0.08%," and "our most recent HRSA audit resulted in no findings." HRSA-2026-0001-1949 at 3. Rochester Regional Health, a nonprofit health system in Rochester, New York, stated that all its 340B hospitals "have been audited by HRSA without any duplicate discount findings." HRSA-2026-0001-2399 at 4; *see also* HRSA-2026-0001-2287 at 2 (University of Rochester Medicine reporting recent audits "yielded no findings or recommendations"); HRSA-2026-0001-1755 at 9 (Sharp HealthCare, a nonprofit health system in San Diego, California, reported that reviews for potential duplicate discounts "have confirmed no duplicate discounts"); HRSA-2026-0001-1413 at 6 (Columbia Memorial Hospital, an Oregon critical access hospital, reporting "no findings in recent HRSA or external audits and no identified duplicate discounts through our internal auditing processes"). As one commenter, UnityPoint Health, a nonprofit health system serving Iowa, Illinois, and Wisconsin, explained, "[a]ssertions from manufacturers suggesting widespread duplication lack factual support and do not reflect the compliance realities of covered entities like ours." HRSA-2026-0001-2283 at 10. HRSA did not grapple with these facts or even search its own audit records to quantify the amount of duplicate discounts in the 340B Program. It instead chose to rely exclusively on unsubstantiated figures supplied by drug companies in their comment letters, citing assertions from self-interested sources as fact.

142. Critically, Defendants' Rebate Program does not even authorize a remedy for the Medicaid duplicate discounts it purports to target. According to the Notice, drug companies are not permitted to deny rebates based on "concerns with diversion or Medicaid duplicate discounts[.]" 91 Fed. Reg. at 48,903. Thus, not only did HRSA fail to *estimate* how much duplicate discounting the Rebate Program would prevent, but the Rebate Program does nothing to *stop* it.

HRSA said that "a rebate model shifts the compliance framework from a reactive enforcement posture to a prospective approach in which verification and claims-level validation occur before the discount is provided." *Id*. at 48,901. But if drug companies cannot prospectively deny claims when they identify a duplicate discount, and instead if "a manufacturer [who] has concerns regarding Medicaid duplicate discounts . . . must raise those concerns directly with HRSA/OPA or utilize the 340B statutory mechanisms, such as audits and administrative dispute resolution," *id*. at 48,903, then the rebate mechanism yields no meaningful *incremental* benefits over the current "retrospective" enforcement system for suspected Medicaid duplicate discounts. Under the very terms of the Program, drug companies must resort to that "retrospective" system regardless. HRSA certainly has not quantified any incremental benefits from its assertedly "prospective" approach, since it did not analyze or explain just how many duplicate discounts its Rebate Program will reduce under this "require-data-submission-but-wait-for-an-audit" approach.

143. Defendants therefore seek to impose, at minimum, hundreds of millions of dollars in annual costs on safety-net providers to remedy a purported harm that Defendants have never measured, through a mechanism that, by the Notice's own terms, cannot remedy it. Agency action premised on an unmeasured problem and ineffectual solution is the paradigm of arbitrary and capricious decision-making.

The Notice Disregards Covered Entities' Data-Driven Estimates of Costs

144. The Notice makes no serious attempt to account for the total costs of the Rebate Program. It never engages data-driven estimates placing administrative costs above $1 billion annually for 340B hospitals. *See* AHA Letter at 11; *supra* ¶¶ 72, 85. In many circumstances, HRSA outright ignored or eliminated entire categories of costs that numerous commenters identified. And

where it addressed firsthand evidence of costs, it dismissed those comments based on conclusory assertions, unquestioning adoption of drug companies' say-so, and manifestly illogical reasoning.

145. **Data-Submission Labor Costs:** The Notice cabins the Program's costs to $523,345,680. 91 Fed. Reg. at 48,893 & n.20. That figure is simple arithmetic: 15,249 covered entities, times 52 weekly submissions, times 5 hours, times $132 per hour, equals $523,345,680. Every input except the entity count is unchanged from the February 2026 ICR, and the 5-hour input is simply HRSA's unexplained 2025 estimate of two hours multiplied by 2.5. But scaling one arbitrary number by another does not produce a reasonable estimate. It only results in a larger arbitrary number. Nothing in the record supplies any other provenance for the number, and Defendants have never offered data supporting one.

146. At most, the Notice offers the conclusory explanation, similar to HRSA's June ICR statement, that its labor estimate "reflects a reasonable median burden across this range of entities." June ICR, 91 Fed. Reg. at 35,990. But HRSA offered no factual support to justify that proposition. Again, the only apparent basis for the 5-hour-per-week number is HRSA's earlier 2-hour-per-week estimate multiplied by 2.5. But HRSA never said that the earlier 2-hour estimate was based on any "median" calculation of record evidence. And as the AHA explained in its response to the ICR, HRSA never identified "what below-5-hours-per-week estimates it received to offset the many above-5-hours-per-week [estimates] it received from many other hospitals and other covered entities. It should not be difficult, for example, for HRSA to produce a chart showing all of the below-5-hours-per-week estimates that would allow the agency's 5-hour estimate to sit at the median." Ex. 1 at 29; *see also id*. (calling on HRSA to "explain why it used a median estimate" at all when "[r]eliance on a median can obscure substantial variation among regulated entities and can materially understate aggregate burden when compliance costs are unevenly distributed.").

147. HRSA's 5-hour-per-week estimate is even more arbitrary because the record overwhelmingly demonstrated why the labor required for data submission alone exceeds five hours per week. For example, commenters explained in detail that the required data live in separate electronic systems, package sizes and NDC configurations conflict, units of measure require manual overrides, and required payer fields are often unavailable. *See supra* ¶¶ 79–80.

148. The Notice addresses none of these specifics. It states only that the Program relies on data that covered entities "already collect, maintain, and retain in the ordinary course," 91 Fed. Reg. at 48,893, and rests that assumption on a self-interested vendor's own representations about its 340B ESP platform, *id.* at 48,891–94, a platform that handles a small fraction of claims and "routinely produces a large number of false denials that require extensive staff review." AHA Letter at 15–17. HRSA likewise never answered the ICR commenters who explained why the agency's assumption that rebate submissions are "materially similar" to claims submitted to Medicare, Medicaid, and commercial payers is wrong. As commenters explained, *see supra* ¶¶ 128–29, those Medicare, Medicaid, and commercial claims are adjudicated electronically at the point of sale, whereas a rebate mechanism requires retrospective file assembly, transmission through a third-party platform, a waiting period, and manual cleanup whenever the automation fails. HRSA has never responded to the comments identifying these fundamental differences, yet the assertion about Medicare, Medicaid, and commercial payers—which one commenter aptly called "load-bearing," Ex. 1 at 19 (Parkview Health)—is repeated multiple times in the Notice. *See, e.g.*, 91 Fed. Reg. at 48,890, 48,894, 48,897.

149. **Reconciliation Costs:** The Notice, in connection with the June ICR, admits that its cost figure covers only the "administrative costs of *reporting* claims data," *id.* at 48,893 (emphasis added), and thus excludes every recurring cost that arises after data are submitted. This exclusion

includes back-end reconciliation, which the administrative record shows will likely be the single most costly component of the Program. *See supra* ¶¶ 80–83, 133–34 (detailing the extensive new costs associated with reconciliation); AHA Letter at 16. Mountain Park Health Center, a federally qualified health center in Arizona, explained: "Reconciliation and denial management are expected to be among the most resource-intensive aspects of the pilot. Current experience with manufacturer restriction platforms and other rebate programs demonstrates that claims frequently require investigation, correction, supporting documentation, resubmission, and follow-up communication." Ex. 1 at 229 (emphasis removed). Legacy Health agreed: "In truth, the increase in administrative burden for our covered entities would be driven by the need to implement rebate reconciliation workflows and not primarily in the data submissions themselves. Rebate reconciliation is labor-intensive work that requires resources." HRSA-2026-0001-1710 at 2–3.

150. HRSA's treatment of reconciliation contradicts itself. The Notice concedes that "most covered entities currently operate under an upfront discount model that reduces the need for post-purchase reconciliation," and that a rebate mechanism will impose new "post-purchase reconciliation" burdens. 91 Fed. Reg. at 48,892. Yet, in the next breath, HRSA said that covered entities "already perform extensive administrative functions under the 340B Program," including "reconciliation activities." *Id.* at 48,892–93. Reconciliation cannot be both a new burden that the Rebate Program creates and a familiar task that covered entities already perform. Because HRSA's reasoning "is internally inconsistent, it is arbitrary and capricious." *ANR Storage Co. v. FERC*, 904 F.3d 1020, 1028 (D.C. Cir. 2018).

151. Even if HRSA could explain this internal inconsistency, its justification for excluding reconciliation costs altogether is doubly flawed. *First*, HRSA is dead wrong that covered entities "already" perform "reconciliation activities." The current "upfront discount" mechanism

does not require any back-end payment reconciliation. Because discounts are currently provided at the point of sale, there is no subsequent rebate to reconcile. HRSA's apparent belief that it does is indefensible.[9] *Second*, HRSA's statement, yet again, ignores the *incremental* effects of its Rebate Program. Simply because covered entities "already" perform some functions does not justify new and costlier requirements.

152. HRSA also insisted, without detail, that existing technology can solve new reconciliation burdens. It insisted that "covered entities . . . routinely utilize TPAs and automated systems for . . . reconciliation activities." 91 Fed. Reg. at 48,893; *see id*. at 48,894 ("[C]ommenters note that established technologies, including automated claims processing, batch data submission, and TPAs, can be leveraged to facilitate rebate submission and reconciliation with minimal manual intervention once implemented."). But consistent with its practice throughout the Notice, HRSA did not identify which commenters asserted that existing technologies can perform this new reconciliation work. Nor did HRSA weigh those mystery sources against the many comments from covered entities saying that manual reconciliation will be necessary for certain tasks. Nor did HRSA identify the specific technology that can do this. Nor did it address, assuming this technology exists, how much incremental cost this new technology would add.

153. Plaintiffs have identified two comments regarding this purported reconciliation technology, both of which are from drug companies. HRSA-2026-0001-2374 at 29 (AbbVie Inc.); HRSA-2026-0001-2226 at 19 (J&J). One cites a Beacon FAQ, stating that the Beacon platform can perform reconciliation of rebates with claims. Notably, Second Sight Solutions, the company behind Beacon, does not cite this technology in its RFI or ICR comment letters. But even if that

[9] For this reason, HRSA's initial concession about the novelty of "post-purchase reconciliation" burdens understates the point. 91 Fed. Reg. at 48,892. As numerous commenters explained, an upfront discount does not merely "reduce" the need for post-purchase reconciliation. Under that mechanism, there is nothing to reconcile at all because the discount is applied at the point of purchase rather than days, weeks, or months later. *See supra* ¶¶ 80–83.

Beacon technology were available and reliable, that does not answer how hospitals can reconcile that information across their *internal* systems when rebates come back from drug companies. Put differently, Beacon reconciliation is not the same thing as reconciliation of a covered entity's own accounting and enterprise resource planning systems. Even if Beacon provides the claim-to-rebate linkage, the covered entity will still incur massive amounts of work (1) importing that information; (2) matching it against its internal records; (3) identifying delays, exceptions, denials, and reversals; (4) assigning payments to the proper internal cost center; and so on. So, if this Beacon product is what HRSA meant by "established technologies" (again, HRSA did not say so itself), then it is no answer to the vast amount of reconciliation work (manual and otherwise) that covered entities will have to do under a rebate mechanism, none of which they had to do under an upfront discount mechanism.

154. At bottom, numerous commenters explained the Rebate Program's unprecedented reconciliation burdens, but the Notice does not respond to that on-the-ground information. It instead excludes *the entire category* of reconciliation and therefore drastically undercounts the administrative costs its Rebate Program will impose.

155. **Staffing Costs:** Hundreds of commenters explained that they would have to hire new staff to comply with the Rebate Program. HRSA's conclusory response was that "any staffing impacts will generally be modest," that "in many cases, additional staffing will be unnecessary because they may be absorbed within existing operational structures or supported through existing third-party arrangements," and that the commenters "provided only estimates of anticipated staffing impacts." 91 Fed. Reg. at 48,891, 48,893. HRSA provided no evidentiary support for the notion that these staffing costs could be replaced by third-party arrangements, whereas dozens of commenters explained that they would need to add staff ***on top of*** these existing arrangements. *See*

Env't Health Tr. v. FCC, 9 F.4th 893, 910–11 (D.C. Cir. 2021) (faulting agency for disregarding a "record contain[ing] substantial information and material from, for example, the American Academy of Pediatrics, . . . medical associations, thousands of physicians and scientists from around the world, and hundreds of people who were themselves or who had loved ones suffering from the alleged effects of RF radiation" (citations omitted)); *Coinbase, Inc. v. SEC*, 126 F.4th 175, 199 (3d Cir. 2025) (discussing and applying the *Environmental Health Trust* holding that the agency failed to address the many "studies and comments provided by the petitioners"); *District of Columbia v. U.S. Dep't of Agric.*, 496 F. Supp. 3d 213, 256 (D.D.C. 2020) ("Notwithstanding the comments alerting the agency to the adverse disparate impact of the Final Rule on minorities, women and persons with disabilities, USDA essentially kicked this problem bucket down the proverbial road . . . . That excuse rings hollow given the many comments supported by 'empirical data.'"). HRSA's conclusory, data-free response to hundreds of individualized comments about incremental staffing costs was not reasoned decision-making.

156. **Vendor, Administrator, and Audit Costs:** HRSA assigned no value at all to increased TPA and vendor fees, IT support, or financial auditing—costs the administrative record places at $150,000 to more than $750,000 per hospital annually, or more than $400 million across 340B hospitals even at the low end. AHA Letter at 9–11. Much like its response to reconciliation costs, HRSA excluded these categories entirely. HRSA's only response, that covered entities "already perform extensive administrative functions," 91 Fed. Reg. at 48,892–93, again fails to acknowledge the *incremental* cost of a new payment mechanism. *E.g.*, *Am. Equity Inv. Life Ins. Co. v. SEC*, 613 F.3d 166, 177–79 (D.C. Cir. 2010) (agency analysis arbitrary and capricious where it failed to compare impact of program against existing "baseline level," *i.e.*, conduct an incremental analysis). Indeed, HRSA even ignored the fact that its own RFI asked for stakeholders

to comment on "incremental" costs, rendering its entire approach internally inconsistent. RFI, 91 Fed. Reg. at 7,289. But when HRSA finally completed its analysis, it somehow characterized these costs as "modest" and "likely to remain low," 91 Fed. Reg. at 48,893–94, in clear contravention of the "considerable evidence in conflict," *Int'l Union, United Mine Workers v. Mine Safety & Health Admin.*, 626 F.3d 84, 94 (D.C. Cir. 2010) (quoting *AT&T Wireless Servs., Inc. v. FCC*, 270 F.3d 959, 968 (D.C. Cir. 2001)).

157. **Start-Up Costs:** HRSA likewise wrote off the entire category of one-time start-up costs. The record quantified these costs at tens of thousands of dollars for the smallest facilities and three to four million dollars for large academic systems, all incurred before a single rebate claim is submitted. HRSA's response was that such costs "will be transitional." 91 Fed. Reg. at 48,893. That says nothing. Of course, "start-up" costs are "transitional"; they are incurred so that covered entities can start their transition to a new payment mechanism. By describing them as "transitional," HRSA admitted that these costs exist, but the agency brushed them aside for a manifestly irrational reason. These "transitional" start-up costs are significant, supported by overwhelming record evidence, and should have been included in HRSA's cost calculations.

158. **"Float" Costs:** The record established that (1) covered entities must advance the full WAC, with individual facilities quantifying advances from hundreds of thousands of dollars to more than $25 million; (2) some wholesalers will require multi-million-dollar prepay escrow accounts regardless of rebate timing; (3) wholesaler payment terms are frequently 5 or 7 days, not 10; (4) the accurate measure of float costs is when the clock starts, not when the 10-day deadline kicks in; (5) some drugs will sit on shelves for long stretches of time; (6) facilities operating on limited days of cash-on-hand would breach bond and debt covenants and divert limited liquid resources away from mission-critical commitments like payroll and patient care; and (7) the

analogous MFP process, run by the same drug companies, routinely pays in thirty to forty-five days rather than the required fourteen and denies or misclassifies between 30 and 75% of claims.

159. HRSA quantified none of this. Nor did it address this record evidence in any meaningful way. It instead wrote that it "expects the cash-flow impacts on covered entities to be minimal" because the 10-day payment requirement "is intended to precede the payment deadlines associated with standard wholesaler payment terms," so that payment to wholesalers, "*in most cases*, would occur after the rebate from the manufacturer is received." *Id.* at 48,895 (emphasis added). Its entire response to the float cost evidence is that "HRSA believes that the Pilot is unlikely to result in unstable cash flow for covered entities, as certain commenters have predicted," *id.* at 48,894, without explaining which specific self-interested commenters made those predictions or analyzing the strength of those commenters' evidence. Nor did it explain why the many covered entity commenters citing these varied float costs are wrong about *their own finances*. *But see AHA I*, 820 F. Supp. 3d at 45 ("[F]inancial forecasts about what costs the 340B entities can bear for a certain period [are] not predicated on any specialized or expert knowledge of the Agency.").

160. HRSA's float analysis rests entirely on two studies funded by the drug industry: a December 2, 2025, IQVIA white paper and a 2021 study by 3 Axis Advisors. *Id.* at 48,894–95 & nn.22–23. Neither was cited in the RFI or the ICRs, nor were they exposed for public comment.

161. The IQVIA paper was funded by the National Pharmaceutical Council, an industry group whose members include manufacturers that will participate in the Rebate Program. In addition, one of the IQVIA study's co-authors sits on the board of Kalderos, a rebate program platform vendor, and documents attached to Kalderos's comment letter reveal that this co-author represented the company during negotiations with HRSA in 2019 and 2020 when Kalderos tried to persuade the agency to approve a rebate mechanism. *See* HRSA-2026-0001-2447 (Kalderos

letter used co-author's name more than 100 times). HRSA never addressed this inherent bias. *E.g.*, *Cboe Futures Exch.*, 77 F.4th at 979 ("We have previously rejected an attempt by the SEC to substitute unquestioning reliance on a regulated entity's submissions for the reasoned analysis the APA requires. Such submissions, we explained, have little supporting value because they express the self-serving views of the regulated entity. If the SEC wanted to rely on MGEX's analyses to connect the grant of exemptive relief with the goal of promoting competition, it needed to critically review and adopt MGEX's submissions or perform its own comparable analysis." (cleaned up)).

162. Substantively, the IQVIA study does not support HRSA's "float cost" predictions. The cited December 2025 IQVIA study models only *interest* costs under an assumed 30-day wholesaler payment term. It does not address more serious costs like liquidity constraints, prepay deposits, credit limits, bond covenants, denied or delayed rebates, or lost COGS, prompt-pay, and sub-ceiling discounts. IQVIA's own comment letter in response to HRSA's RFI concedes that its studies measured only "financing (interest) costs" and that actual wholesaler payment terms "are not publicly available." HRSA-2026-0001-1688 at 2–3. Despite HRSA never having cited the IQVIA study in the RFI or indicating that it would rely so heavily on it when evaluating "float" costs, America's Essential Hospitals and others offered specific, forceful critiques of the study in their comments. *See* HRSA-2026-0001-1994 at 15–16 (America's Essential Hospitals). The Notice never acknowledges or refutes the critiques.

163. Worse still, HRSA relied on the December 2025 paper while ignoring the same authors' April 17, 2026 update, published more than three months before the Notice. That revised study undermines HRSA's conclusion. Critically, the April 2026 study shortened the assumed payment term to 10.5 days because it received information from stakeholders that real-world terms varied from 7 to 14 days. This shortened payment term produced materially higher interest-cost

figures. The revised study estimated $53.7 million in annual interest costs for *just the ten 2026 drugs*. HRSA did not include that $53.7 million in its cost-benefit analysis, however. Nor did it include any interest-cost estimates for all 25 drugs in the current Rebate Program.

164. The 3 Axis study on which HRSA relied is five years old, was commissioned by a similarly biased vendor (Kalderos), and examined only covered entities that use contract pharmacies. It rests on the assumption that a month's worth of inventory arrives on day one, and half the month's claims are dispensed that same day. But these assumptions are completely untethered from reality, where, for example, hospitals take delivery on recurring wholesaler schedules, not in a single-day shipment, and hospitals dispense prescriptions continuously across the month. Even Kalderos did not cite this study in its own comment letter (likely because of these faulty assumptions). *See* HRSA-2026-0001-2447 (Kalderos). HRSA nonetheless extended 3 Axis's conclusions to *every category* of covered entity, not just contract pharmacies, when it unreasonably concluded that "float" costs would be minimal.

165. The Notice also suggests that enforcement of the Rebate Program's purported guardrails will solve for "float costs." That is wrong. Such costs exist independent of delays or denials. To be sure, delays or denials *extend* the "float" cost associated with these interest-free loans to drug companies, but the covered entities will suffer "float" costs even if every drug company were to pay rebates on time for every claim.

166. The Rebate Program's skeletal (at best) enforcement regime is flawed in other ways. For example, the Program's specified enforcement regime is entirely discretionary based on whether HRSA decides to remove a drug company from the Program. The Notice says only that HRSA "could review a sample" of transactions and "initiate removal proceedings" if 5% or more of rebates were delayed or denied without justification. 91 Fed. Reg. at 48,895. For starters, that

approach presupposes the delays and erroneous denials that commenters predicted, yet provides no remedy for the "float" cost hospitals would be forced to carry in the meantime. Put differently, HRSA admitted that it will tolerate the improper delay or denial of tens of millions of dollars in statutory discounts so long as they remain *under* 5%, and at best, HRSA merely retains the option of acting when those delays and denials *exceed* 5%. Thus, despite effectively assuming that *some* delays and denials will occur (something it must do given the track record in the MFP Program that was described in the administrative record, *see supra* ¶¶ 99, 158), HRSA nowhere discussed them in its "float cost" or cash flow analysis. Nor did it account for how any as-yet undescribed manufacturer-removal proceedings would prolong existing delays and denials, extending covered entities' cash-flow and liquidity burdens even further.

167. To make matters worse, HRSA's purported enforcement backstop is of little value because, as of now, there is none.

a. HRSA merely retains the option of entirely removing drug companies from the Program if a 5% threshold of delays and denials is exceeded. But that is all HRSA said about enforcement. It provided no standard by which it will evaluate removal, for example. It provided no information about how a removal process would work. It did not identify a removal decisionmaker or even a person who will receive complaints from covered entities in the first instance.

b. HRSA's recent updates are no more reassuring. In recently published FAQs, HRSA addresses the question "[w]hat is the process to resolve issues or denials for 340B rebates under the Pilot?" by saying, "[e]ach manufacturer has committed to addressing these issues in good faith. Covered entities should work with the manufacturer's point(s) of contact and the rebate model IT

platform vendor to resolve disputes." *See* HRSA Rebate Program Webpage. The FAQ also suggests that HRSA will publish an online form to report complaints "[i]f the issue remains unresolved after good-faith efforts," although that "link [is] forthcoming." *Id.* Again, there is no identification of how or when these disputes will be settled or who will ultimately be responsible, indicating covered entities need to be prepared to wait months or years to recover rebates.

168. Defendants are—yet again—"fly[ing] the plane before they build it," *AHA I*, 820 F. Supp. 3d at 46–47, at least with respect to how they will prevent delays, denials, or other violations of Rebate Program guardrails. Until that plane is built, however, the absence of any real enforcement will impose cash flow, liquidity, and legal costs on covered entities that HRSA did not account for. Based on the administrative record, HRSA must reasonably assume that there will be at least *some added costs* related to delays and denials, just as there are in the MFP Program. HRSA cannot erase those costs from the equation simply because it promises more information about dispute resolution 30 days after the Program begins or provides the cold comfort that it "*could* initiate removal proceedings of that manufacturer from pilot participation for non-compliance" when denials exceed 5% of the total rebates. 91 Fed. Reg. at 48,895 (emphasis added). Those inevitable delays and denials will amount to substantial expenses that appear nowhere in HRSA's "float cost" analysis. When the record demonstrates that such delays and denials are currently occurring at double-digit percentages in the MFP Program, HRSA easily could have put a conservative dollar figure on those costs for its cost-benefit analysis. It did not.

169. **Deadlines to Submit Rebates and New Costs:** Defendants waved away "float" costs in part by pointing to three design features of the Rebate Program: unit-level rebate processing, which lets a covered entity seek a rebate as individual units are dispensed rather than

only after a full package is replenished; a fifteen-day transition grace period at the outset of the Pilot; and a 45-day window in which to submit rebate data after dispense. None of these eliminates the costs, and some clearly impose more costs upon safety-net facilities.

a. Unit-level processing, which allows a covered entity to submit for reimbursement before a whole drug package is exhausted, imposes more administrative costs upon a covered facility by forcing it to submit more claims for reimbursement. And requiring more claims on the front-end makes it more likely that hospitals will take longer to submit them; this will further delay the 10-day clock from starting, leading to the same cash flow concerns. Moreover, unit-level processing has no effect when units purchased at WAC price languish undispensed on the shelf, because no rebate is available until dispense. Given that safety-net hospitals and other providers must retain stocks of these important drugs, *supra* ¶¶ 95, 109, the "float cost" will persist as long as the drugs remain in inventory undispensed. This fact was raised in comments but ignored.

b. The fifteen-day transition grace period, for its part, caps relief at two unreplenished packages and runs for only fifteen days. 91 Fed. Reg. at 48,902. But because drugs can sit on the shelf for months, the grace period will lapse while the hospital is still carrying the full acquisition cost of drugs it has not dispensed and on which it cannot yet seek a rebate. It is likely that many more than two packages will be impacted, causing covered entities to lose significant amounts of 340B discounts.

c. Worst of all, the Notice requires all rebate requests to be submitted within 45 days of dispense. *Id*. Although HRSA framed this as a way to limit costs, commenters made clear it would *do the opposite*—by eliminating the ability to collect discounts where unavoidable circumstances delay submissions. Commenters made clear that, for various reasons, pharmacies "often need more than 45 days to dispense an entire package of a drug." HRSA-2026-0001-1619 at 5 (CommUnityCare Health Centers, a federally qualified health center in Austin, Texas). Every drug that lingers past the forty-fifth day could be a *permanent loss* of the 340B discount.

d. The 45-day design feature also ignores how claims will be processed. Beacon—the Second Sight Solutions platform through which approved drug companies will process rebate claims—runs every submission through a battery of "back-end validations," and a claim that fails any one of them is invalidated. Beacon, *Back-end Validations* (Dec. 19, 2025), https://support.beaconchannelmanagement.com/en/articles/13186516-back-end-validations. Beacon states that the 45-day deadline "does not reset to the date of the initial claim submission." *Id*. A hospital that submits on day 40 and is told its claim is invalid therefore has only five days to diagnose the problem, correct it, and resubmit—or *permanently forfeit* the statutory discount. Meanwhile, because the drug company's 10-day payment clock restarts only upon a "completed data submission," 91 Fed. Reg. at 48,903, every invalidation resets the drug company's clock while the covered entity's clock keeps running. Beacon may also invalidate claims reflecting "aberrant quantities," meaning

quantities that exceed a number of "expected thresholds" that Beacon does not disclose, that no public standard defines, and that a covered entity has no stated means to contest. Beacon, *Back-end Validations*. Nothing in the Notice authorizes these consequences, and HRSA's burden analysis says nothing about them.

170. **Loss of Cost-of-Goods-Sold, Prompt-Pay, Sub-Ceiling, and Other Discounts:** The Notice acknowledges the "loss of wholesaler prompt-pay or cost of goods discounts" only once, in its summary of what commenters wrote. 91 Fed. Reg. at 48,892. But HRSA never returned to that category of costs, even though the record identified and quantified them, *see supra* ¶¶ 104–05, and even though it is a permanent loss that cannot be recouped. Those undisputed prompt-pay, cost of goods, and other forgone discounts translate into millions of dollars that HRSA "unreasonably understated" in its cost-benefit analysis. *Chamber of Com. of the U.S.*, 820 F. Supp. 3d at 491 (citation omitted).

171. **Costs to Patients and Communities:** The record identified concrete threats to patients, including free or discounted drugs that will no longer be provided; patients transferred or turned away; service lines closed; hospitals carrying little or no inventory of drugs because WAC price will far exceed the 340B price; national pharmacy chains withdrawing from 340B pricing for covered drugs; clinic hours shortened or days closed; and more. The Notice recites some of these consequences but illogically concludes that HRSA "does not anticipate that the Pilot will materially impair covered entities' . . . ability to furnish services to patients." 91 Fed. Reg. at 48,899. Most glaringly, HRSA acknowledged comments stating that patients may have to "go elsewhere and potentially travel far distances to obtain necessary medications—a problem that is particularly acute for rural communities," *id.* at 48,898, but it offered no response and failed to

include those non-economic harms in its cost-benefit analysis. *See Council of Parent Att'ys & Advocs., Inc. v. DeVos*, 365 F. Supp. 3d 28, 53–54 (D.D.C. 2019) (cost analysis must account for "the cost of delay on children, parents, and society"); *Md. People's Couns. v. FERC*, 761 F.2d 768, 776 (D.C. Cir. 1985) (Scalia, J.) ("Even unquantified factors, however, cannot be dismissed without further inquiry where their impact is both evident and massively significant.").

172. Astonishingly, HRSA nowhere acknowledged that the $500-plus million in data-submission costs alone will lead to patient harms because spending that money on submitting claims data makes it unavailable for free or discounted drugs and other patient care. This silence is particularly inexplicable because this Court last year emphasized the "downstream effect[s]" of having to divert hundreds of millions of dollars in administrative expenses away from patient services. *AHA I*, 820 F. Supp. 3d at 46.

173. Although Defendants need not "weigh the burdens imposed on each and every entity that makes up the Public Health Service," "the fact that the 'pilot' program impacts them all calls for something more than casual indifference to localized impacts." *Id.* at 45 n.5. In this year's Rebate Program, however, Defendants showed the same "casual indifference." The Notice analyzes the impact on no particular community, region, or facility type, despite clear evidence setting forth those localized impacts. *See supra* ¶ 113. Likewise, HRSA did not address counties risking their only labor-and-delivery unit or inpatient behavioral-health beds, *see supra* ¶ 111, rural patients facing longer travel to obtain lifesaving care, *see supra* ¶ 112, or the many healthcare providers that wrote of the particular challenges the Rebate Program will pose for their own "localized" communities, *see supra* ¶ 113.

174. **Timing/Financial Environment:** The Notice ignores the financial environment into which HRSA is launching the Program. Multiple commenters asked HRSA to consider this

important problem when deciding whether to renew its Rebate Program for 2027. HRSA did not do so. The Notice does not mention the OBBBA, Medicaid reductions, coverage losses, increases in uncompensated care, tariffs, or dwindling hospital cash-on-hand or margins. Nor did HRSA defend its decision to move forward with a Rebate Program *at this time*, in the face of these cascading challenges. On that topic, like so many others, HRSA is silent.

The Notice Rejects Every Less Burdensome Alternative on Conclusory and Circular Grounds

175. Commenters presented numerous alternatives to the Rebate Program. And Defendants themselves told two federal courts of appeals that drug companies "have other options available to them" and "alternate means to deduplicate discounts." AHA Letter at 40 (citation omitted); *see AHA II*, 164 F.4th at 37 ("[T]he federal government has indicated that manufacturers have alternative methods to address the previously described duplication issue."). Yet Defendants rejected every cheaper, less burdensome, and equally viable alternative.

176. Defendants dismissed a neutral clearinghouse as "not explicitly authorized under the 340B statute." 91 Fed. Reg. at 48,900. This was the extent of HRSA's legal analysis. It did not (1) explain its legal reasoning despite commenters' express requests to provide it or (2) explain why CMS may operate a comparable "340B repository" while HRSA supposedly cannot. *See* AHA Letter at 48 ("HHS has not, however, publicly presented its legal reasoning, and there is serious reason to question it."); *id.* at 47–49 & n.49; HRSA-2026-0001-1914 at 6, 16–17 (comment of AAMC, to same effect).

177. HRSA's only other justification for a rebate mechanism instead of a clearinghouse is based on rank speculation. It claimed that a rebate mechanism is superior to a clearinghouse because, "unlike a clearinghouse, a rebate model by its very nature incentivizes covered entity compliance as a prerequisite to receiving 340B discounts." 91 Fed. Reg. at 48,900; *see id.*

(describing a clearinghouse as "in substance, an enhanced claims modifier system operating under a different name," and rejecting it because, "[l]ike claims modifiers, a clearinghouse would depend on covered entities to accurately and completely report 340B transaction data to the intermediary, and on the intermediary to relay that information to manufacturers and payers in a timely and standardized manner"). But HRSA provided no actual evidence that covered entities will not comply with an independent clearinghouse, nor did it acknowledge that CMS has proposed to make its clearinghouse mandatory.

178. In fact, HRSA's discussion of these purported "incentives" is cut-and-pasted, with only a single word change, from a comment letter submitted by the Pharmaceutical Research and Manufacturers of America ("PhRMA"). *Compare* 91 Fed. Reg. at 48,900 ("As manufacturer commenters have observed, unlike a clearinghouse, a rebate model by its very nature incentivizes covered entity compliance as a prerequisite to receiving 340B discounts."), *with* HRSA-2026-0001-1895 at 14 (comment letter from PhRMA, writing that "[u]nlike a clearinghouse, a rebate model, by its very nature, incentivizes covered entity compliance as a precursor to receiving the 340B discount."). HRSA did not critically examine PhRMA's speculation or ask covered entities themselves whether they would participate in a clearinghouse. It simply reproduced PhRMA's statement verbatim to justify its speculation about incentives and, on that basis, dismissed a cheaper, viable clearinghouse alternative that HHS itself recently implemented (and is considering making mandatory).

179. Had HRSA critically assessed PhRMA's speculation about incentives, it would have realized that speculation was wrong. If the choice is between an independent clearinghouse and this costly Rebate Program, the incentives strongly favor participating in a clearinghouse. HRSA's speculation about "incentives" is especially problematic given the administrative record.

Numerous covered entities (and the organizations that represent them) affirmatively suggested an independent clearinghouse as an alternative to the Rebate Program. *See, e.g.*, AHA Letter at 46–49; HRSA-2026-0001-2391 at 2 (American Society of Health-System Pharmacists); HRSA-2026-0001-1965 at 32–34 (National Association of Community Health Centers); HRSA-2026-0001-2139 at 16 (UNC Health); HRSA-2026-0001-2382 at 10 (Indiana University Health); HRSA-2026-0001-2262 at 3 (Washington State Hospital Association); HRSA-2026-0001-2274 at 5 (Greater Lawrence Family Health Center); HRSA-2026-0001-1886 at 1 (University of Iowa Health Care); HRSA-2026-0001-2246 at 3 (Piggott Health System); *see also* HRSA-2026-0001-2415 at 4 (Rush University System for Health, urging that any platform used under a rebate model be "operated by a truly neutral third-party clearinghouse"). Although covered entities suggested that alternative, HRSA did not explain why it would not follow through on this. Thus, HRSA cannot reasonably dismiss an independent clearinghouse by simply reproducing verbatim PhRMA's uninformed speculation about "incentives."[10]

180. HRSA's remaining justification for rejecting alternatives is circular. HRSA rejected other alternatives because "the 340B discount is provided upfront and compliance is assessed only retrospectively," thus any alternatives that preserve the upfront mechanism "would not inform whether rebates are an efficient means of effectuating the 340B ceiling price, . . . fail[ing] to advance the central purpose of the Pilot." 91 Fed. Reg. at 48,890, 48,900–01. In other words, any alternatives to a Rebate Program are inadequate because they are not a Rebate Program. That is

[10] HRSA failed to address drug companies' incentives for participating in the Rebate Program. Because participation is voluntary for manufacturers, each one may choose which eligible drugs to include. On information and belief, multiple manufacturers withheld an eligible drug for fear of losing market share to competing products outside the Rebate Program, even though at least one drug company included a different eligible drug. If duplicate discounts were as costly as drug companies claim, manufacturers would subject all of their eligible drugs to a rebate mechanism. That they did not confirms that the duplicate discount problem is overstated and that drug companies embrace a rebate mechanism only where it serves their competitive interests.

entirely self-justifying. An agency cannot define its objective as the action itself and then reject every alternative for failing to be that action.

181. HRSA's objective must be defined independently from the Program itself. Here, HRSA identified that objective as reducing duplicate discounts. But its circular justification (testing the Program for testing's sake) does nothing to explain why the proposed alternatives would not achieve that independently defined objective. For example, HRSA's rejection of "more intensive audits and oversight" consists of the tautological assertion that such tools are "inherently reactive," *id*. at 48,899, 48,901, which is another way of saying they are not rebates.

182. Finally, HRSA's rejection of a voluntary or smaller pilot on "selection bias" grounds is speculative and conclusory. *Id.* HRSA never considered whether a representative pool would, in fact, volunteer. It never addressed whether a representative pool could be incentivized to participate, including by having drug companies pay the costs for the volunteers. And it did not explain why mere statistical tidiness justifies conscripting *all* 15,249 covered entities.

The Notice Does Not Appropriately Assess Reliance Interests

183. The Notice's treatment of reliance interests also violates controlling law. In the prior litigation, Defendants conceded that covered entities' "decades of industry reliance" on the upfront discount mechanism was "significant." *AHA I*, 820 F. Supp. 3d at 42. Both this Court and the First Circuit concluded that HRSA was required to weigh that reliance interest. *Id.* at 43; *AHA II*, 164 F.4th at 33. But now, rather than comply with this obligation, HRSA simply zeroed out the reliance interests it once deemed significant. HRSA declared that it "does not agree that exclusive reliance on an upfront discount model is reasonable," because the statute authorizes 340B pricing via rebate, and "covered entities' reliance interests . . . do not outweigh the significant benefits of proceeding with the Pilot." 91 Fed. Reg. at 48,888–89.

184. That the statute offers HHS discretion whether to approve a rebate mechanism does not erase decades of reliance. The existence of an unexercised statutory option has no bearing on the reliance that an agency's own conduct engendered. Reasonable reliance is measured by what the agency did, not by the mere existence of discretion the agency did not invoke for thirty-three years. Covered entities' reliance interests were established by unbroken agency practice, by HRSA's own 1994 and 1998 pronouncements, and by the agency's court filings defending upfront discounts as recently as 2025, *see supra* ¶¶ 50–51, 56, none of which the Notice confronts. Referring to a heretofore-unexercised statutory provision without accounting for *what caused* covered entity reliance does not reflect appropriate consideration of reliance interests. *See, e.g.*, *Regents*, 591 U.S. at 30–33.

185. The Notice's alternative finding—that reliance interests "do not outweigh the significant benefits of proceeding with the Pilot," 91 Fed. Reg. at 48,889—also lacks merit, but for a more fundamental reason. As noted above, *supra* ¶¶ 138–41, HRSA does not even know the scale of the duplicate discount problem the Rebate Program is meant to address, or whether duplicate discounting occurs at any material rate at all. HRSA blindly credited drug-industry estimates it never tested, while disregarding HHS's own audit findings to the contrary. An agency that cannot say how large a problem is cannot conclude that addressing it outweighs anything, least of all thirty-three years of reliance interests and the imposition of hundreds of millions of dollars in new costs that result from that "significant" reliance. *AHA I*, 820 F. Supp. 3d at 42.

The Notice Does Not Grapple with Important Aspects of the Problem

186. The Notice also leaves unaddressed several significant problems that commenters presented. Three examples stand out:

a. HRSA failed to address the financial environment in which it would start the new Rebate Program. Multiple commenters cited these financial headwinds, yet HRSA ignored them altogether. *See supra* ¶¶ 114, 174. At no point did it address or justify why the Rebate Program is needed *now*.

b. HRSA provided scant details concerning an operational dispute-resolution mechanism. *See supra* ¶¶ 166–68. The Notice and other disclosures identify no objective standard for when to enforce, name no ultimate decisionmaker, prescribe no procedure, and set no deadline for action or compliance, even though commenters warned that, absent HRSA's active involvement, "there is little hope that disputes will actually get resolved," and that drug companies would be affirmatively incentivized to delay and deny. AHA Letter at 51.

c. The Notice does not address the operational and structural problems commenters documented with the third-party vendor platforms that would administer the Rebate Program. Commenters report, based on firsthand experience, that they "encountered serious problems" with the Beacon platform, "including issues with terms and conditions, shifting data requirements, and inadequate customer service." HRSA-2026-0001-0023 at 4 (Iroquois Healthcare Association); *see also* HRSA-2026-0001-0044 at 4 (MyMichigan Health, a nonprofit health system with 340B hospitals, reporting similar issues); HRSA-2026-0001-1394 at 12 (Clinica Family Health & Wellness, a federally qualified health center in Colorado, stating that its "current experience in working with [Beacon] has been nothing short of flawed and frustrating"); *accord* AHA Letter at 25 (AHA, noting that Second Sight's

340B ESP platform "often experiences problems, including false denials and delays").

HRSA Rejected All Firsthand Information About Its Cost Estimate Without Explaining Its Own Calculation

187. Comments on the June ICR, the source of the $523,345,680 figure, were due July 15, 2026. While over 250 comments were submitted during that comment period, HRSA issued the 2026 Notice on August 3, 2026, without addressing those comments and without revising its estimate. 91 Fed. Reg. at 48,893–94. Instead, HRSA responded to the ICR comments on August 4, 2026, the day after the Notice was published, in a revised supporting statement for the ICR. Supporting Statement. OMB concluded its review and approved the collection without change the following day, August 5, 2026. *See* OMB, ICR History, OMB Control No. 0906-0117.

188. The Supporting Statement adheres to the 5-hour-per-week calculation of costs for covered entities first calculated in February 2026, without providing any more details or explanation as to the methodology behind that calculation and without addressing the comments noting that the assumption was unsupported and unexplained. *See* Supporting Statement at 11. The Supporting Statement changes the pharmacist wage rate ($132 to $135.50), such that HRSA's own total reached $537,222,270 to submit claims, nearly $14 million more than the $523,345,680 figure the Notice cited the day before. *Compare* Supporting Statement at 11 ($537,222,270 quoted in the Supporting Statement) *with* 91 Fed. Reg. at 48,893 & n.20 ($523,345,680 quoted in the Notice).

189. The Supporting Statement also changes its description of the 5-hour-per-week calculation from the "median" burden upon covered entities to an "average" burden, without acknowledging that important change. *Compare* Supporting Statement at 11 ("average burden") *with* June ICR, 91 Fed. Reg. at 35,990 ("median burden"). An average and a median are different things. *E.g.*, *Ferguson v. Allen*, 2020 WL 2572176, at *9 n.57 (N.D. Ala. May 21, 2020) ("The

terms 'average,' 'mean,' and 'median' can be confusing. The average and arithmetic mean are calculated by adding together all numerical values in a data set, and dividing that sum by the number of terms in the set. . . . In contrast, the median is the middle numerical value in an ordered set of data." (emphasis removed)); *see also S. Cal. Edison Co. v. FERC*, 717 F.3d 177, 182 (D.C. Cir. 2013); *Can. Ass'n of Petroleum Producers v. FERC*, 254 F.3d 289, 298–99 (D.C. Cir. 2001). But the Supporting Statement offers no explanation for those inconsistencies. Nor does it describe the more general methodology HRSA continued to use throughout this process to calculate labor costs for data submission.[11]

190. The remainder of the Supporting Statement confirms that HRSA did not meaningfully consider the comments. HRSA acknowledged that it received 180 comments in response to the February ICR and 263 in response to the June ICR. *Id.* at 6. It also acknowledged that the comments "primarily addressed the estimated paperwork burden," and that "[n]umerous commenters submitted organization-specific burden estimates that substantially exceeded HRSA's estimate." Supporting Statement at 6–7. HRSA then disregarded those estimates in a single paragraph by asserting that "many estimates assumed reporting requirements that will not be included in [the] Pilot," *id.* at 7, without (1) identifying a single example of such a misassumption, (2) acknowledging the many comments that did not make such assumptions and instead calculated burden based on the correct reporting and other programmatic requirements, or (3) providing an

[11] For example, when HRSA was relying on a median figure to determine its 5-hour-per-week labor estimate, the AHA urged HRSA to provide "what below-5-hours-per-week estimates it received to offset the many above-5-hours-per-week it received from many other hospitals and other covered entities. It should not be difficult, for example, for HRSA to produce a chart showing all of the below-5-hours-per-week estimates that would allow the agency's 5-hour estimate to sit at the median." Ex. 1 at 29. HRSA never provided that below-5-hour list. Nor did it provide any list or other data that would support its new claim that the 5-hour-per-week figure was the "average" of labor hours submitted.

additional period for commenters to correct any purported misassumptions. The Supporting Statement merely asserts in conclusory terms that

> HRSA continues to believe that the estimated burden reasonably reflects the average paperwork burden associated with the information collection, across more than 15,000 covered entities, while recognizing that actual burden may vary among respondents, and is a modest compliance cost for a program that has reached $100 billion in annual purchases in 2025. HRSA will continue to evaluate implementation experience during the Pilot to inform future burden estimates.

Id. at 7; *see* 91 Fed. Reg. at 48,893 (referring to and citing the ICR for $523,345,680 data-submission cost calculation).

191. The Supporting Statement's response on reconciliation costs, the category many commenters identified as the single largest omission from the estimate, is non-responsive. HRSA acknowledged that "[n]umerous commenters cited operational experience under existing manufacturer reporting platforms and the MDPNP as evidence that reconciliation and denial management represent a substantial portion of the overall burden." Supporting Statement at 8. But rather than estimate that burden and add it to the ICR, HRSA answered that manufacturers will be required to provide "real-time rebate status reporting" and "document the basis for rebate denials," and asserted that these features would "reduc[e] unnecessary administrative burden associated with reconciliation and dispute resolution." *Id.* HRSA still offered no recognition that it understood what work reconciliation would require, despite extensive comments explaining it to the agency. *See supra* ¶¶ 80–83, 133–34. HRSA also conflated "real-time rebate status reporting" within the third-party vendor's system with the work that covered entities will need to do on the back end to ensure rebated payments get to the right place. *See supra* ¶ 81. And HRSA did not provide any estimate of the "reduc[ed]" hours that reconciliation would entail—with or without those features. It simply left the reconciliation burden at zero.

192. The Supporting Statement likewise declines to calculate or account for start-up and training costs, even though the definition of "burden" listed in the document's definition section includes time "to train personnel." Supporting Statement at 10. HRSA never explained why it excluded them.

193. The Supporting Statement omits technology and system costs, even though its own definition of "burden" includes time "to develop, acquire, install, and utilize technology and systems." *Id.* HRSA never explained why it excluded them.

194. Thus, despite the thousands of comments submitted by hundreds of safety-net hospitals and other covered entities about the costs and impact the Rebate Program would have on rural hospitals and patient care, HRSA remained steadfastly stuck on the same labor-hour estimate that it fashioned before it received the comments. It avoided serious consideration of the mountains of firsthand cost information it received from covered entities, ignored entire categories of costs it admitted would be borne by rural and other safety-net hospitals, and offered cursory responses to points it acknowledged cast serious doubt about its own estimation of impact.

HRSA Approved Ten Drug Companies' Rebate Plans

195. On October 1, 2026, HRSA announced that it had approved rebate plans from ten drug companies—AbbVie, Amgen, Astellas, AstraZeneca, Bristol Myers Squibb, Boehringer Ingelheim, GlaxoSmithKline, Merck, Pfizer, and Teva—covering 18 drugs. These included widely prescribed anticoagulant, diabetes, oncology, respiratory, and immunology medications. *See* HRSA Rebate Program Webpage. Each approved plan takes effect January 1, 2027.

196. Neither the approvals nor the accompanying materials update the Notice's cost-benefit analysis. HRSA did not revise its 5-hour-per-week labor estimate, did not account for the reconciliation, start-up, or float costs that commenters documented, and did not quantify any

benefit. It did not acknowledge the updated IQVIA study, the financial environment facing covered entities, or the "standpoint" standard that Congress instructed HRSA to apply. HRSA simply announced that "[e]ach plan met the requirements outlined in the Federal Register Notice," without further details. *Id.* Every defect in the Notice therefore remains. And, as described below, the approved plans and HRSA's new guidance add to the Program's costs by eroding the few guardrails the Notice purported to erect.

197. The approved plans confirm the massive costs that commenters described and HRSA ignored. Every approved plan designates the same third-party platform—the "Beacon Rebate Model Platform," operated by Second Sight Solutions—as the sole channel through which covered entities must register, submit claims data, and receive rebates. HRSA, in approving ten plans that run exclusively through Beacon, did not acknowledge, let alone respond to, the many comments criticizing Second Sight Solutions' existing 340B ESP platform for false denials and manual reconciliation work. *See supra* ¶¶ 83, 129, 132, 186(c).

198. Although HRSA assured covered entities that the drug company plans would adhere to a prescribed set of common standards, 91 Fed. Reg. at 48,902, the approved plans in fact have significant differences—and thereby impose additional costs. For example, several plans adopt a "first-to-file" rule under which, if more than one covered entity submits a claim for the same dispense, only the first conforming submission is honored and all others are denied—regardless of which entity actually holds the valid 340B claim. In addition, the plans do not even agree on when the Notice's 10-day payment clock starts—some run it from submission, others only from a "complete" and "validated" submission, with no stated limit on how long "validation" may take. And some plans exclude federal holidays from the 10-day clock, even though the Notice limited the period to calendar days. Each of these variations adds confusion and creates new

administrative work, potential disputes, and potential denials—none of which HRSA considered when it issued the Notice.

199. Several plans also incorporate the drug companies' existing contract-pharmacy restrictions as conditions of payment. For example, Merck's plan limits rebate eligibility to transactions that comply with Merck's "340B Program Integrity Initiative" and declares non-compliant contract-pharmacy claims "ineligible for rebates." Bristol Myers Squibb requires that a dispensing pharmacy be "eligible under BMS's 340B program obligations and contract pharmacy policy." Amgen's Beacon validations test each pharmacy against "the manufacturer's contract pharmacy policy." Those conditions contravene the Notice's directive that plans "must ensure that 340B rebates are not denied based on eligibility or compliance concerns," *id.* at 48,903, and HRSA's own statement that rebates "may not be denied for covered-entity eligibility," HRSA Rebate Program Webpage.[12] Beacon confirms the point: it describes its back-end validations as enforcing not only "HRSA['s] 340B program requirements" but also, separately, "pharmaceutical manufacturer conditions." Beacon, *Data Validations Overview* (Dec. 19, 2025), https://support.beaconchannelmanagement.com/en/articles/13186016-data-validations-overview. The platform through which rebates will flow thus enforces exactly the compliance conditions the Notice says cannot be grounds for denial. What's more, company contract pharmacy policies differ greatly, further adding to the variation across manufacturers that the Notice promised would not exist.

[12] They also create a collision with the laws of Maine and other States—including Arkansas and North Dakota, where Plaintiffs' members operate—that prohibit drug companies from restricting 340B contract-pharmacy arrangements. Courts, including in Maine, have upheld these laws. *E.g.*, *AstraZeneca Pharms. LP v. Harris*, 2026 LX 544820, at *38 (E.D. Ark. Sept. 29, 2026); *AstraZeneca Pharms. LP v. Frey*, 2026 WL 2145194, at *1 (D. Me. July 27, 2026). But whether and how covered entities in those States will be rebated for contract-pharmacy dispenses is left entirely unaddressed. More generally, each company has a different contract pharmacy policy, so like other aspects of the approvals, this introduces significant variations across manufacturer requirements that will increase administrative complexity and costs.

200. HRSA's approval of Beacon also underscores a flaw in its Notice. In minimizing the costs of its Rebate Program, HRSA highlights a commenter who stated that covered entities "are already using its platform to collect claims data, that thousands of covered entities have registered on the platform, and that covered entities have reported fully onboarding in less than ten minutes through a self-service process." 91 Fed. Reg. at 48,892. That commenter was Kalderos, not Second Sight Solutions, which operates the chosen platform. HRSA-2026-0001-2447 at 6 ("Kalderos' Truzo platform further reduces the administrative steps required to effectively implement a 340B rebate model. The platform is designed to be fully self-service and many covered entities have reported fully onboarding in less than 10 minutes."). In reality, joining and operating under *Second Sight's Beacon platform* is costly and burdensome. To take just one example, AbbVie's plan explains that signing up for Beacon requires a covered entity to complete Beacon's Know Your Business process, provide corporate documentation such as articles of incorporation and an IRS CP 575 letter, provide bank-account information and a bank letter, and undergo a penny-test/microdeposit verification process. HRSA nowhere considers this start-up work in its cost-benefit analysis.

201. Alongside the approvals, HRSA posted a new set of "Frequently Asked Questions" on the same webpage. HRSA Rebate Program Webpage. Far from curing the defects described above, the FAQs confirm them.

a. *First*, the FAQs again recite the "pilot" label while promising only a "Final Evaluation" to be published by April 30, 2028—sixteen months after the Program takes effect. *Id.* HRSA does not say whether the Program will continue to operate between the end of its first year and publication of the Evaluation. But if it does, that additional period would add hundreds of millions of dollars

of costs on top of the billion-plus-dollar costs that will be borne by safety-net hospitals. Nor does the FAQ explain exactly what the April 30, 2028 evaluation will measure, or what, if anything, it could change. It vaguely speaks of "quantitative measures" and "qualitative feedback" but provides no meaningful indication of what constitutes a successful test.

b. *Second*, the FAQs state that "[m]anufacturers may choose to include all covered entity types as part of their rebate models or provide exceptions to certain covered entities," and that "[t]hat information will be included in the respective manufacturers' approved plan." *Id*. That statement cannot be squared with the Notice's statement that a "narrowly tailored . . . participant pool . . . would constrain the agency's ability to assess how a rebate model functions across the broader 340B environment." 91 Fed. Reg. at 48,901.[13]

c. *Third*, HRSA also now acknowledges what the Notice (but not the August Supporting Statement) ignored: that reconciliation is real work. The FAQs state that covered entities "should have access to the real-time rebate status of a claim, so they can easily reconcile claims submitted with rebates paid." HRSA Rebate Program Webpage. But access to a vendor's status screen is not reconciliation. Because claims are de-identified before they reach Beacon, a covered entity must use a vendor-assigned "unique ID" to link each Beacon record back to the identifiable record in its own systems, match the two, and

[13] The Notice also rejected the suggestion that HRSA conduct a pilot with fewer or less popular drugs, stating that "further limiting the number of drugs included in the Pilot would reduce the agency's ability to evaluate rebate administration and duplicate discount prevention in the context of the MDPNP and other overlapping pricing programs." 91 Fed. Reg. 48,901. But HRSA's October 1 approvals undermine its own rationale. HRSA ultimately approved applications for only 18 drugs (and only 10 of 13 drug companies), but it never tried to reconcile that decision with its prior reason for rejecting a less burdensome alternative.

then pursue every claim that is denied, delayed, or underpaid. Likewise, this does not capture the burdensome reconciliation work that must be done within a covered entity's internal systems to ensure that rebates get to where they belong.

Thousands of Hospitals Will Be Immediately and Irreparably Harmed by the 340B Rebate Program

202. HRSA's repeated violations of basic administrative law requirements will irreparably harm thousands of covered entities, especially the most vulnerable safety-net hospitals.

203. Beginning January 1, 2027, covered entities collectively will be required to spend at least $537,222,270 every year in new administrative costs, a figure Defendants themselves calculated, and one that by their own description covers *only* the cost of submitting claims data. Supporting Statement at 11; *see also* 91 Fed. Reg. at 48,893. Those costs are unrecoverable; covered entities cannot seek damages from the federal government to recoup them.

204. Nor are those costs a distant prospect. Months before the Program takes effect, covered entities are already spending to hire staff and build systems so that they can comply, exactly as they did before the 2025 Program was enjoined. Even the smallest safety-net hospitals must hire new employees or pull existing ones away from other work to meet the Rebate Program's administrative demands. Plaintiff Nathan Littauer Hospital will need to hire at least one additional full-time employee. Plaintiff EMMC estimates roughly 80 additional staff hours each week just to oversee and correct its third-party administrator's reports, and will need two additional analysts at approximately $123,000 a year in total compensation. Plaintiff Unity Medical Center will need the equivalent of one to two specialized full-time employees. Plaintiff Dallas County Medical Center, which administers its entire 340B program with a single employee, will, at minimum, have to divert a former pharmacy technician from community education and outreach.

205. Vendors are raising their prices, too. EMMC's third-party administrator has quoted an additional $1,000 per month for pharmacy claims submission alone. Nathan Littauer anticipates approximately $63,000 in additional annual third-party administrator, compliance-vendor, and consulting fees. After making those commitments, EMMC, Nathan Littauer, and Unity Medical Center *still* do not believe they can be ready to implement the Rebate Program by January 1, 2027.

206. The Rebate Program also forces covered entities to pay the full wholesale acquisition cost of covered drugs upfront and then wait to be repaid. For hospitals already in the red, the sums are staggering. EMMC must advance approximately $14 million a year. Even with millions of dollars in 340B savings this year, EMMC still operates on negative margins, as it has since 2019, and it has already budgeted a $6.1 million increase in bad debt and free care for 2027 as patients lose MaineCare coverage under the OBBBA. Plaintiff Unity Medical Center, a 14-bed critical access hospital with an operating margin under 3%, must float approximately *$2.5 million* to pay for the relevant 340B drugs. Dallas County Medical Center must float approximately $1.5 million, roughly ten times its annual outlay under the upfront discount model. And Plaintiff Nathan Littauer, which has run double-digit negative margins for more than five years, would have to float nearly triple its current outlay if all twenty-five drugs were approved for 2027.

207. HRSA's 10-day rebate window does not solve the problem. The clock does not start until a manufacturer receives a complete claim, and Plaintiff MHA's members estimate that the gap between dispensing a drug and receiving the rebate will run from roughly 11 days to as long as a month. Nathan Littauer's experience suggests even that estimate is optimistic: under the MTF rebate program in which it already participates, claims are supposed to be paid in 14 days but in practice take roughly 30 to 90 days, depending on the manufacturer and the drug.

208. Wholesalers will not wait that long. Payment terms among Plaintiff MHA's members range from 7 to 15 days, and certain of Dallas County Medical Center's wholesalers require payment *daily*. EMMC buys on net-15-day payment terms, which would leave it fewer than 5 days to assemble and submit a complete claim if it hoped to be repaid before its wholesaler invoice came due, a schedule it is not confident it can meet.

209. This financial squeeze also threatens bond and loan covenants at hospitals with thin reserves. The median Maine hospital has just 9.3 days of cash-on-hand. EMMC, for example, has just 52.33 days of cash-on-hand, and its parent system is bound by a bond covenant requiring at least 45 days. A $14 million annual advance puts EMMC in danger of breaching that covenant or, at minimum, being forced to draw on a line of credit, with interest, to pay its wholesaler on time. Once a covered entity exceeds its credit limit, its wholesaler stops filling orders, not just for drugs in the Rebate Program but for every 340B drug the entity buys.

210. Covered entities operating on tiny (if any) margins and limited cash-on-hand do not have these resources to spare. Every dollar spent complying with the Rebate Program is a dollar they cannot spend on patient care. To absorb these costs, covered entities across the country will have to terminate or shrink programs providing free or discounted drugs, close service lines, hire fewer clinicians, and put off replacing outdated equipment. Patients will bear the consequences.

211. The Plaintiffs and their members are already facing those choices:

a. MHA's member hospitals use their 340B savings to provide financial assistance to patients who cannot afford care, to run community health clinics in schools, nursing homes, and other easy-to-reach locations, and to offer lifesaving opioid intervention services such as naloxone, Suboxone, and methadone. They cannot sustain those services at current levels if the Rebate Program takes effect. Some

members also report that they would have to stop subsidizing physician practices or drop behavioral health, substance use treatment, or labor and delivery services altogether.

b. Dallas County Medical Center recently opened a cancer telehealth clinic that saves patients a 2-hour round trip to the nearest oncologist, and it runs an intensive outpatient psychiatric program for seniors that is the only mental health counseling available in the county. The Rebate Program puts both at risk.

c. Plaintiff Unity Medical Center may be unable to sustain its recently opened cardiac and pulmonary rehabilitation services.

d. Plaintiff Nathan Littauer Hospital has been gifted property for a new primary care clinic, but the Rebate Program puts that project in jeopardy.

e. EMMC is the primary tertiary referral hospital for northern and eastern Maine. Operating losses have already forced it to close its audiology, pain, and walk-in clinics and to cut more than 125 full-time-equivalent positions. The Rebate Program threatens further cuts.

212. Looming administrative and float costs are also forcing Plaintiffs to pause capital projects that their patients need. Dallas County Medical Center has put on hold at least $35,000 in critical boiler room maintenance, a wheelchair-accessible shower the hospital still lacks, and a telehealth clinic in a local school for children who otherwise lack access to care. Nathan Littauer Hospital has put its pharmacy build-out on hold. Unity Medical Center has paused the long-planned modernization of its inpatient pharmacy. EMMC risks losing the capital it needs to replace critical equipment, including imaging, endoscopy, and cardiac catheterization lab equipment. And MHA's members have been forced to delay or cancel planned emergency department renovations,

electronic medical record installations, and expanded emergency transportation. Each of these delays irreparably harms Plaintiffs, their patients, and their missions.

213. The burdens are severe enough that some covered entities are doubtful they can stay in the 340B Program at all. DFD Russell Medical Centers, a federally qualified health center serving rural central and western Maine, has concluded that it would have to leave the 340B Program if Defendants' rebate mechanism takes effect. The Rebate Program's staffing cost alone would exceed DFD Russell's entire remaining benefit of the 340B Program. Nathan Littauer has written into its third-party administrator contract renewal an option to reconsider its participation in the 340B Program if the Rebate Program does not make it financially whole, something it has never had to do before. And Dallas County Medical Center has concluded that the financial pressure from the Rebate Program could force it to leave the 340B Program altogether.

COUNT I — ADMINISTRATIVE PROCEDURE ACT
(Agency Action Not Based on Relevant Factors; Failure to Respond to Relevant and Significant Public Comments)

214. Plaintiffs repeat, re-allege, and incorporate all allegations in preceding paragraphs.

215. Defendants' establishment and January 1, 2027 implementation of the revised 340B Rebate Model Pilot Program, and their approval of drug company plans to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

216. Agency action must be based on "consideration of the relevant factors," *State Farm,* 463 U.S. at 43. Consistent with that principle, an agency's decision must be "connected to the purpose and concerns of relevant law." *Gulluni*, 85 F.4th at 82 (citing *Judulang*, 565 U.S. at 64).

217. Congress supplied the relevant factors here. When considering what payment mechanism to approve, Congress "expects that the Secretary of HHS, in developing these agreements, will use the mechanism that is the most effective and most efficient from the

standpoint of each type of 'covered entity.'" *Novartis Pharms. Corp.*, 182 F.4th at 1030 (quoting H.R. Rep. No. 102-384, pt. 2, at 16 (1992)).[14] The D.C. Circuit noted the "standpoint" standard days before HRSA issued the Notice. *Id.*

218. Numerous commenters cited the "standpoint" standard and explained why HRSA's balancing framework contradicts Congress's instruction for how the agency must exercise its discretion in choosing a payment mechanism. *See, e.g.*, HRSA-2026-0001-2437 at 2 (340B Health, noting that balancing the interests of covered entities and manufacturers is a "false premise" and that "Congress anticipated that the Secretary would use the rebate or discount that is the most effective and most efficient from the standpoint of each type of covered entity" (cleaned up)); HRSA-2026-0001-1991 at 21–22 (Penobscot Community Health Care, citing "standpoint" standard and noting that a rebate mechanism does "not meet the 'least burdensome' requirement"); AHA Letter at 2–3.

219. HRSA has long recognized this statutory standard. HRSA applied the "standpoint" standard during the only prior occasion when it approved a rebate mechanism, for ADAPs in 1997 and 1998. *See supra* ¶ 51. It repeatedly invoked the standard in legal briefs last year. *See supra* ¶ 56. HRSA even quoted the "standpoint" standard in the Notice. 91 Fed. Reg. at 48,884–85.

[14] The First Circuit has repeatedly relied on committee reports to set the standard Congress intended to govern an agency's exercise of delegated discretion. *E.g., Melone v. Coit*, 100 F.4th 21, 32–33 (1st Cir. 2024) (relying on "[r]elevant legislative history"—a committee report, H.R. Rep. No. 97-228, at 19 (Sept. 16, 1981)—to identify Congress's intended limitation on agency discretion and reviewing agency action against that limitation for arbitrariness); *Grinspoon v. DEA*, 828 F.2d 881, 893–94 (1st Cir. 1987) (looking to "standard contained" in committee report to determine permissible standard for agency's exercise of statutory discretion and reviewing agency's methodology against that standard for arbitrariness); *see also Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 19 (1st Cir. 2020) (citing language from a House Report as providing a "meaningful tool" for judicial review when rejecting a claim that there were no "judicially manageable standards"); *cf. Page v. Donovan*, 727 F.2d 866, 868 (9th Cir. 1984) ("Even if the statute is drawn broadly, review is not precluded if the legislative history offers standards that a reviewing court can apply.").

220. Despite reciting the "standpoint" standard, the Notice fails to apply it. Instead, the Notice adopts a decisional framework of the agency's own invention: that "HRSA must balance covered entities' longstanding reliance on the upfront discount model against the need to ensure effective program oversight, safeguard the benefits of 340B pricing, and maintain program integrity," and must "weigh competing policy concerns." *Id.* at 48,887–88.

221. Nothing in the 340B statute authorizes the Secretary to balance away the interests of covered entities. In substituting its arbitrary balancing framework for the congressional "standpoint" standard, HRSA "relied on factors which Congress has not intended it to consider," *State Farm*, 463 U.S. at 43; *see Judulang*, 565 U.S. at 55, 64, and failed to evaluate the Rebate Program under the standard Congress prescribed for choosing payment mechanisms.

222. The 2026 Notice also impermissibly inverts HRSA's prior regulatory approach. Rather than choosing a payment mechanism that is "most effective and most efficient" from the standpoint of covered entities, Defendants chose the more effective mechanism *for drug companies*. HRSA adopted its unprecedented balancing approach without displaying any awareness of that change. *See FDA v. Wages & White Lion Invs., L.L.C.*, 604 U.S. 542, 568 (2025); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) ("An agency may not, for example, depart from a prior policy *sub silentio* or simply disregard rules that are still on the books.").

223. Separately, the Rebate Program is "unmoored" from the overall "purposes and concerns" of the 340B statute. *Judulang,* 565 U.S. at 64. The statute's undisputed purpose is 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 (1992). HRSA acknowledged this purpose in the Notice, *see* 91 Fed. Reg. at 48,884–85, but

nowhere grappled with the fact that diverting at least half a billion dollars away from patient care and comprehensive services is disconnected from and damaging to that purpose.

224. Instead, HRSA merely recited the general proposition that "no statute pursues a single policy at all costs, and we are not free to rewrite this statute (or any other) as if it did." *Id.* at 48,889 (quoting *Advoc. Christ Med. Ctr. v. Kennedy*, 605 U.S. 1, 19 (2025)). But that conclusory explanation ignores two critical points.

225. *First*, many covered entities explained that the Rebate Program would put them at risk of having to close service lines (thereby providing less, rather than more, comprehensive care) or even close their doors altogether. *See supra* ¶¶ 106–13.[15] Others explained that they would need to leave the 340B Program because of its administrative and other burdens. *See supra* ¶ 213.[16] Even if a statute does not pursue its purpose at "all" costs, Congress would not have wanted to impose *these costs* given the 340B statute's undisputed overall purpose and concern. Separate and apart from Defendants' unreasonable cost-benefit analysis about the *incremental* benefits of the Rebate Program itself, *see infra* Count III, taking a half-billion dollars away from "more eligible patients and providing more comprehensive services," H.R. Rep. No. 102-384, pt. 2, at 12 (1992), unreasonably "frustrates, rather than advances, the statutory mandate," *Marasco & Nesselbush,*

[15] *See also* HRSA-2026-0001-1585 at 4 (comment from Jackson Hospital and Clinic, a nonprofit community hospital in Montgomery, Alabama, that "[c]urrently the savings from 340B is crucial for our survival"); HRSA-2026-0001-1417 at 2 (Edwards County Medical Center, a rural critical access hospital in Kinsley, Kansas, noting that "[t]he reality is" the hospital "could close its doors if 340B dollars cannot continue to help us on our bottom line"); HRSA-2026-0001-2406 at 12 (comment from Boston Medical Center Health System that "[w]e believe widespread use of rebates would put BMCHS at risk of insolvency. Essential systems like ours are operating at negative margins already; we would have no choice but to take immediate, drastic survival measures.").

[16] *See also* HRSA-2026-0001-0106 (Community Memorial Healthcare, a small critical access hospital, stating that "[t]his increase in cost surrounding our currently very compliant 340B program may put us at risk of continuing in the 340B program"); HRSA-2026-0001-1522 at 2 (comment from Cook County Hospital District that "[b]ased on the proposed rebate framework, [North Shore Health] would likely be forced to discontinue participation in the 340B program. We do not have the staffing capacity or infrastructure required to implement and sustain the additional administrative processes.").

LLP v. Collins, 6 F.4th 150, 178 (1st Cir. 2021). It is fatally unmoored from Congress's purpose in enacting the 340B statute.

226. *Second*, Defendants ignored that *this Court* has held that preventing duplicate claims and preserving program integrity are subsidiary objectives in service of the program's actual purpose, not a co-equal end that may be pursued at the expense of the covered entities or their patients. *See PhRMA*, 2026 WL 184504, at *9 n.10 ("Protecting manufacturers against duplicate claims and otherwise preventing fraud are subsidiary goals to the objective of the 340B program, which is to subsidize the cost of drugs to underserved populations."). Defendants' decision to balance *nonstatutory* objectives with the undisputed *statutory* purpose is arbitrary and capricious. *See Georgia v. Brooks-LaSure*, 2022 WL 3581859, at *17–20 (S.D. Ga. Aug. 19, 2022) (holding CMS acted arbitrarily and capriciously by relying on nonstatutory "health equity" objective and explaining that agency may not "depart from" statutory factors "to achieve some other goal"); *see also Gresham v. Azar*, 950 F.3d 93, 104 (D.C. Cir. 2020), *vacated and remanded with instructions to dismiss as moot sub nom. Becerra v. Gresham*, 142 S. Ct. 1665 (2022) (mem.) ("While . . . it is not arbitrary or capricious to prioritize one statutorily identified objective over another, it is an entirely different matter to prioritize non-statutory objectives to the exclusion of the statutory purpose."); *Nat'l Mining Ass'n v. EPA*, 59 F.3d 1351, 1364 (D.C. Cir. 1995) (finding APA violation when an agency's decision "would sacrifice a statutory objective in pursuit of ends that, at least as presented in argument to us, have not been justified . . . in terms of . . . provisions of the Act" and where agency "subordinate[d]" the statutory purpose to "other considerations not approved by Congress"); *Farmers Union Cent. Exch., Inc. v. FERC*, 734 F.2d 1486, 1500, 1501 (D.C. Cir. 1984) (agency action must remain "true to the congressional mandate" and may not

allow other policy considerations to produce an "improper departure from the basic congressional mandate").

227. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of the APA.

COUNT II — ADMINISTRATIVE PROCEDURE ACT

(Rebate Program Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law — Failure to Adequately Consider the Costs of the Rebate Program, Including Administrative Costs and Float, Liquidity, and Financing Costs; Explanation Runs Counter to the Evidence Before the Agency)

228. Plaintiffs repeat, re-allege, and incorporate all allegations in preceding paragraphs.

229. Defendants' establishment and January 1, 2027 implementation of the revised 340B Rebate Model Pilot Program, and their approval of drug company plans to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

230. Under the APA, an agency must "examine the relevant data and articulate[] a satisfactory explanation for its action, including a rational connection between the facts found and the choice made." *California v. U.S. Dep't of Educ.*, 132 F.4th 92, 98 (1st Cir. 2025) (quoting *State Farm*, 463 U.S. at 43) (internal quotation marks omitted). As part of that exercise, an agency may not "unreasonably understate[] the costs of" a regulatory program. *Chamber of Com. of the U.S.*, 820 F. Supp. 3d at 491; *see also Presidents' All. on Higher Educ. & Immigr.*, 2026 WL 2690098, at *15 ("An agency acts arbitrarily and capriciously when it 'fail[s] adequately to quantify certain costs.'" (quoting *Bus. Roundtable*, 647 F.3d at 1148–49)). "Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions," and "[n]o regulation is 'appropriate' if it does significantly more harm than good." *Michigan*, 576 U.S. at 752–53. This Court has already held these principles

applicable in this context: HRSA must "identify benefits that 'bear a rational relationship to the . . . costs imposed,'" and its failure to consider the full scope of costs before committing to a rebate mechanism is "fatal under the APA." *AHA I*, 820 F. Supp. 3d at 45.

231. Defendants have failed to satisfy these legal obligations in three ways, ignoring or unreasonably discounting (1) the full scope of administrative costs of the Rebate Program, (2) the many costs of "floating" the full list price of covered drugs while awaiting repayment of discounts owed under the 340B statute, and (3) the non-economic costs to patients and communities.

232. Defendants committed these legal errors by, among other things, (1) failing to engage the detailed evidence, based on deep institutional knowledge, that was submitted by the covered entities that will actually bear these three categories of costs, while (2) uncritically adopting the drug companies' and their vendors' mischaracterization of those costs. After all, an agency may not simply "t[ake] [a commenter's] word for it," *Susquehanna*, 866 F.3d at 445–47. If it relies on outside analysis, an agency must "critically review" that analysis or "perform its own." *In re NTE Conn., LLC*, 26 F.4th 980, 988 (D.C. Cir. 2022) (alterations removed); *Affirmed Energy, LLC v. FERC*, 166 F.4th 1070, 1083 (D.C. Cir. 2026); *Bloomberg L.P. v. SEC*, 45 F.4th 462, 473 (D.C. Cir. 2022). And it must "explain[] why" it finds the outside submission persuasive and why it credited some comments over others. *Cboe Futures Exch.*, 77 F.4th at 979 (internal quotation marks omitted); *see also AARP v. EEOC*, 267 F. Supp. 3d 14, 32 (D.D.C. 2017).

233. The administrative record contains detailed, covered entity-specific calculations from stakeholders with firsthand knowledge of hospital operations. These commenters established that administrative costs for 340B hospitals alone would exceed $1 billion annually, and that individual entities will bear costs many times the estimate presumed by HRSA. The submissions from covered entities were the product of "deep institutional knowledge and experience, not mere

conjecture." *Cath. Legal Immigr. Network*, 513 F. Supp. 3d at 174. "Grappling with relevant data requires more than a mere recitation of unfavorable evidence without further explanation." *Cigar Ass'n of Am. v. FDA*, 132 F.4th 535, 540 n.2 (D.C. Cir. 2025). Yet Defendants dismissed covered entities' cost calculations as "only estimates," while arbitrarily crediting conclusory and conjectural assertions of drug companies and their vendors. 91 Fed. Reg. at 48,891–94.

234. ***Administrative costs.*** The only covered-entity cost Defendants quantified, $537,222,270 per year, is expressly limited to "reporting claims data." Supporting Statement at 11; 91 Fed. Reg. at 48,893 & n.20. Defendants acknowledged that massive figure excludes reconciliation, rebate tracking, denial and dispute management, one-time start-up and IT integration costs, vendor and TPA fees, training costs, and every other administrative cost category the comments document. 91 Fed. Reg. at 48,893–94 & n.20; June ICR, 91 Fed. Reg. at 35,990. Commenters described these excluded categories of cost in scrupulous detail. Nevertheless, Defendants assigned no monetary value to any of these excluded categories, offering only conclusory assurances that they would be "modest." 91 Fed. Reg. at 48,893–94. Nor did Defendants revisit that figure, or any excluded category, when they approved the specific drug company plans that covered entities must implement.

235. That "fail[ure] adequately to quantify the certain costs or to explain why those costs could not be quantified" is arbitrary and capricious. *Bus. Roundtable*, 647 F.3d at 1148–49; *see also Bloomberg L.P.*, 45 F.4th at 472 ("[T]he agency did not provide a reasoned response to Bloomberg's comments that FINRA failed to quantify the direct and indirect costs of its proposed data service (or explain why certain costs could not be quantified)."); *Presidents' All. on Higher Educ. & Immigr.*, 2026 WL 2690098, at *15–16 (finding an agency acted unlawfully by excluding entire categories of costs that commenters identified). Likewise, HRSA's assertions about costs

are "conclusory or unsupported suppositions" that do not reflect reasoned decisionmaking. *NetCoalition v. SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010); *see also Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 708 (D.C. Cir. 2014).

236. Multiple categories of administrative costs were unreasonably omitted altogether. But an agency "may not simply disregard an entire category of obvious costs." *Fla. E. Coast Ry., LLC v. Fed. R.R. Admin.*, 186 F.4th 822, 866 (11th Cir. 2026).

a. **Reconciliation Costs:** Numerous commenters explained how and why reconciliation costs would exceed submission costs. *See supra* ¶¶ 80–83, 133–34. Commenters also explained that these reconciliation requirements could not be solved by existing technology, let alone cheaply or freely, and so significantly more than five hours a week of labor would be needed to also perform this reconciliation work. The Notice excludes such costs, under the theory that covered entities "already perform extensive administrative functions under the 340B Program," including "reconciliation activities." 91 Fed. Reg. at 48,892–93. But that response irrationally fails to recognize that a rebate model introduces reconciliation requirements that *never before existed* under an upfront discount model. It also ignores the *incremental* effects of its Rebate Program, which was what commenters described to the agency. Defendants acted unreasonably by not quantifying reconciliation costs, providing a reasoned response to their existence, or otherwise appropriately considering them.

b. **Start-Up Costs:** Despite substantial record evidence of considerable start-up costs, Defendants unreasonably failed to include them in their cost-benefit

analysis for the circular reason that they are "transitional." *Id.* at 48,893–94. In fact, the Notice explains that there will be "legitimate startup activities" and that start-up costs are "inherent to the adoption of a new operational approach," *id*., but Defendants did not quantify them, provide a reasoned response to their existence, or otherwise appropriately consider them.

c. **Vendor and Training Costs:** Despite substantial record evidence of significant vendor and training costs, Defendants unreasonably failed to include them in their cost-benefit analysis because "participation in the 340B Program has always entailed some level of compliance and operational cost. Covered entities derive significant financial benefit from participation in the Program." *Id.* at 48,894. The Notice acknowledges that covered entities will be forced to bear at least some vendor and training costs, but Defendants did not quantify the increase in costs, provide a reasoned response for their exclusion, or otherwise appropriately consider them.

237. Defendants also authorized the Rebate Program after commenters showed that the 5-hour-per-week assumption that gave rise to the $537,222,270 figure was unexplained, unsupported, unreasonably low, and contrary to the overwhelming weight of evidence submitted by the very covered entities that would actually perform this labor. Defendants finalized their action without revising or justifying this labor-hour estimate, which itself was nothing more than a rote multiple of an unsubstantiated estimate that this Court found to be unsatisfactory last year. For HRSA to reach this exact same labor-hour figure again and again, it necessarily must have concluded that every single commenter that offered a higher labor-hour estimate misunderstood

the program's features or was wrong about the program's effects on its own operations. That itself is irrational.

238. When HRSA did respond, in a supporting statement submitted to OMB the day *after* the Notice was published, it dismissed the abundant countervailing evidence in conclusory terms, asserting that HRSA "continues to believe that the estimated burden reasonably reflects the average paperwork burden," "while recognizing that actual burden may vary among respondents." Supporting Statement at 7. But an agency's "statement of 'belief' is not a reasoned analysis." *Presidents' All. on Higher Educ. & Immigr.*, 2026 WL 2690098, at *19. HRSA's "own *ipse dixit* . . . is no substitute for reasoned decision-making," *Ctr. for Biological Diversity v. EPA*, 141 F.4th 153 (D.C. Cir. 2025) (Katsas, J., concurring in part and dissenting in part); *see generally Stein, Inc. v. NLRB*, 2025 WL 655081, at *3 (D.C. Cir. Feb. 28, 2025) (per curiam) ("[A]n assertion so 'conclusory' does not amount to reasoned decision making." (citing *Am. Clean Power Ass'n v. FERC*, 54 F.4th 722, 727 (D.C. Cir. 2022))). In addition, HRSA's refusal to ever explain the underlying support for its 5-hour-per-week calculation fails the APA's requirement that agency action be "reasonable and reasonably explained." *Ohio v. EPA*, 603 U.S. at 292 (quoting *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021)).

239. Moreover, because HRSA arrived at substantially the same labor-hour figure it reached before, its cost analysis warrants "a somewhat greater degree of scrutiny," given "the danger that an agency, having reached a particular result, may become so committed to that result as to resist engaging in any genuine reconsideration of the issues." *Shands Jacksonville Med. Ctr., Inc. v. Azar*, 366 F. Supp. 3d 32, 48 (D.D.C. 2018) (quoting *Greyhound Corp. v. ICC*, 668 F.2d 1354, 1358 (D.C. Cir. 1981)); *see Regents*, 591 U.S. at 21–23 (an agency's post-remand explanation "must be viewed critically"); *Wint v. Yeutter*, 902 F.2d 76, 81 (D.C. Cir. 1990)

("Because the [agency], on remand, both altered its original rationale and arrived at the same result initially vacated by the district court, close consideration of the Department's action is warranted.").

240. ***"Float," liquidity, and financing costs***. The defining feature of a rebate mechanism is that covered entities must pay drug companies sums far exceeding what they owe, "essentially functioning as an interest-free loan from the hospitals to the manufacturers," and wait for repayment. *AHA II*, 164 F.4th at 32. This Court held that the 2025 record's silence on these "float" costs established Plaintiffs' likelihood of success. *AHA I*, 820 F. Supp. 3d at 44–45. The 2026 Notice's analysis that costs will be "minimal" is an equally unreasonable explanation under the APA.

241. The Notice's conclusion that float costs will be "minimal" relies entirely on two industry-funded studies, the December 2025 IQVIA paper and the 2021 3 Axis study, neither of which was raised in the RFI or ICRs, and both of which rely on narrow, outdated data. Both studies also only address small pieces of the "float cost" problem (interest and contract pharmacies, respectively), leaving the Notice entirely barren about a range of other costs associated with the "float." *See supra* ¶¶ 93–105.

242. Reliance on "two relatively unpersuasive studies" against the weight of contrary record evidence is arbitrary and capricious. *Bus. Roundtable*, 647 F.3d at 1150–51; *Window Covering Mfrs. Ass'n v. CPSC*, 82 F.4th 1273, 1291 (D.C. Cir. 2023) (agency may not credit one interested party over hundreds of contrary commenters without explanation). And because neither study was identified in the RFI or otherwise exposed for public comment, HRSA violated the rule that "the most critical factual material that is used to support the agency's position" must "be made public in the proceeding and exposed to refutation." *Air Transp. Ass'n of Am. v. FAA*, 169 F.3d 1,

7 (D.C. Cir. 1999) (emphasis removed); *see also Chamber of Com. v. SEC*, 443 F.3d 890, 900–01 (D.C. Cir. 2006); *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 236–37 (D.C. Cir. 2008).

243. HRSA contended that its 10-day payment requirement solves for any "float cost" concerns. But the Notice ignores the abundant record evidence that contradicts this premise. Commenters identified wholesaler terms of 5 to 7 days; prepay deposits of tens of millions of dollars per quarter; days-cash-on-hand levels as low as four days; severe liquidity concerns in spite of a 10-day payment premise; diversion of limited reserves to drug companies (rather than payroll or other expenses); bond covenants this liquidity drain would breach; and drug companies' documented failure to pay MFP refunds within even a 14-day window. IQVIA's (unacknowledged) April 2026 second study itself notes that the 10-day premise is contradicted by many stakeholders. Commenters also explained that the 10-day payment requirement was less valuable given that the clock for rebating starts after a claim is submitted. An agency "cannot ignore evidence that undercuts its judgment; and it may not minimize such evidence without adequate explanation." *Genuine Parts*, 890 F.3d at 312.

244. Much like with administrative costs, at least three categories of "float" costs were unreasonably eliminated altogether:

a. **COGS, Prompt-pay, and Other Lost Discounts:** Despite substantial record evidence of these significant costs, Defendants unreasonably failed to include them in their cost-benefit analysis. Indeed, the Notice itself briefly mentions COGS discounts, but never returns to them. Thus, even though the record reflects that these lost discounts will cost covered entities millions of dollars annually, Defendants did not quantify them, provide a reasoned response to their existence, or otherwise appropriately consider them.

b. **Interest Costs:** The one type of "float cost" that the IQVIA studies acknowledged was interest costs. But despite relying on the outdated version of that study, Defendants unreasonably failed to include *any* interest costs in their cost-benefit analysis. The April 2026 follow-up IQVIA study estimates $53.7 million in such costs for only 10 drugs, but Defendants did not quantify such costs for their expanded 25-drug program, provide a reasoned response to their existence, or otherwise appropriately consider them.

c. **Delay/Denial Costs:** Defendants cannot rationally assume that there will be no rebate delays or denials that would extend the "float" timeline or leave covered entities entirely without rebates they are owed. Drug companies and their vendors, even if they were not financially interested, will never have a perfect record of providing rebates on time and as deserved. *See Dep't of Com. v. New York*, 588 U.S. 752, 785 (2019) ("[W]e are not required to exhibit a naiveté from which ordinary citizens are free." (internal quotation marks omitted)). But more than that, the administrative record is replete with real-world evidence explaining why such delays and denials will inevitably occur, particularly given the recent track record with the MFP Program. HRSA still provides no meaningful remedy to the hospitals left waiting for their rebates, suffering the liquidity and cash flow injuries that HRSA nonetheless deems "modest." An agency may not ignore "practical realities," and here, the practical reality is that there will be some number of delays and denials. *Marasco & Nesselbush,* 6 F.4th at 176–77. Defendants did not quantify

delay/denial costs, provide a reasoned response to their existence, or otherwise appropriately consider them.

245. ***Costs to patients and communities.*** Defendants failed to reasonably consider the non-monetary costs of the Program. Instead, they insisted that "[a]s a result" of various Program design features, "HRSA does not anticipate that the Pilot will materially impair covered entities' . . . ability to furnish services to patients." 91 Fed. Reg. at 48,899.

246. HRSA ignored these costs even though this Court recognized in the prior litigation that imposing $400 million in administrative costs would have "the downstream effect causing them to cut back services." *AHA I*, 820 F. Supp. 3d at 46. Here, HRSA itself conceded $537 million in data-submission costs yet nowhere considered the "downstream effect" on patient services.

247. If the prior judicial record was not enough for Defendants to take seriously patient costs, the administrative record documented these non-economic harms with remarkable specificity: inability to provide free or discounted drugs; minimal or no inventory of drugs whose WAC exceeds their 340B price fivefold; patients transferred or turned away; a county's only labor-and-delivery unit and inpatient behavioral-health beds closed; rural telehealth, cardiac rehabilitation, and diabetes education shuttered; national pharmacy chains' withdrawal from 340B pricing; and much more. *See supra* ¶¶ 106–13, 171, 211; HRSA-2026-0001-2169 at 1 (Premier Community HealthCare Group, a federally qualified health center serving Hernando and Pasco Counties, Florida, explaining that under a rebate model it "would be forced to purchase medications at the full Wholesale Acquisition Cost (WAC), which can be 4 to 5 times higher than the 340B ceiling price"); *see generally* AHA Letter at 6 n.5, 29–32, App. B; HRSA-2026-0001-1914 at 8 (comment of AAMC). HRSA neither calculated nor weighed any of these costs. Nor did it analyze the impact on any particular community, region, or facility type, demonstrating the same

"casual indifference to localized impacts" this Court found unacceptable last year. *AHA I*, 820 F. Supp. 3d at 45 n.5. That is, once more, an unreasonable underestimate of costs, a failure to consider "an important aspect of the problem," *State Farm*, 463 U.S. at 43; *Ohio v. EPA*, 603 U.S. at 293–94, and a conclusion that goes against the overwhelming weight of the record evidence.

248. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of the APA.

COUNT III — ADMINISTRATIVE PROCEDURE ACT
(Rebate Program Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law — No Calculated Benefit Articulated; Purported Benefits Are Unsubstantiated and Bear No Rational Relationship to the Costs Imposed)

249. Plaintiffs repeat, re-allege, and incorporate all allegations in preceding paragraphs.

250. Defendants' establishment and January 1, 2027 implementation of the revised 340B Rebate Model Pilot Program, and their approval of drug company plans to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

251. 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.*, 60 F.4th at 965, 973 (quoting *State Farm*, 463 U.S. at 43) (emphasis added). An agency must conduct a "reasoned calculation of the costs and benefits." *Presidents' All. on Higher Educ. & Immigr.*, 2026 WL 2690098, at *16. "[A] serious flaw" in a cost-benefit analysis "can render the [resulting] rule unreasonable." *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012); *see Thompson v. Clark*, 741 F.2d 401, 405 (D.C. Cir. 1984). "[V]ague and conclusory assertions" of benefit do not justify significant costs. *Chamber of Com. of the U.S.*, 820 F. Supp. 3d at 489. And "a reasoned decision would explain why any unquantified benefits cannot reasonably be quantified." *GPA Midstream Ass'n v.*

U.S. Dep't of Transp., 67 F.4th 1188, 1200 (D.C. Cir. 2023); *Tex. Indep. Ginners Ass'n v. Marshall*, 630 F.2d 398, 411 (5th Cir. 1980).

252. HRSA "unreasonably overstat[ed] the benefits" of the Rebate Program. *Chamber of Com. of the U.S.*, 820 F. Supp. 3d at 491. The only numbers in the Notice's discussion of benefits are borrowed, stale, speculative, and self-interested: drug company assertions from 2019 that Medicaid/340B duplicate discounts "amounted to as much as $1.5 billion annually," 91 Fed. Reg. at 48,887, and drug-industry comments "suggesting that duplicate discounts *may* affect up to approximately 25% of 340B drug transactions," *id.* at 48,898 (emphasis added). These figures were drawn nearly verbatim from the drug companies' comment letters, but the Notice nowhere acknowledges or grapples with that fact. Equally problematic is the fact that the drug companies themselves have been inconsistent with their numbers, sometimes reducing their claims of "billions" of dollars of deduplication costs to "potentially millions" when arguing before federal courts of appeals. *See* Doc. 2158962 at 2, *Novartis Pharms. Corp. v. Kennedy*, No. 25-5177 (D.C. Cir. Feb. 12, 2026) (describing the deduplication costs as "potentially millions").

253. HRSA has its own audit information that would illuminate the scale of any duplicate discounts but never acknowledged its possession of that information. "HRSA conducts approximately 160 audits of 340B hospitals annually—or about 6% of the 340B hospital field." AHA Comment Letter on Application Process for the 340B Rebate Model Pilot Program, at 8–12 (Aug. 27, 2025), *incorporated by reference in* AHA Letter at 42 n.47. In fact, Plaintiff EMMC received notice on September 28, 2026, that HRSA will be auditing it over the next several months. Defendants' historic audit records should have been more than enough evidence for the agency to form its own understanding of any duplicate discount problem without having to lift stale and speculative data from drug company comment letters. HRSA cited none of this audit evidence,

even as commenters urged the agency to do so and described their own experiences with clean audits. *See supra* ¶¶ 140–41 (describing comments that laid out audit results on deduplication both holistically and individually from covered entities). HRSA failed to acknowledge, let alone evaluate, contrary evidence, drawn from HHS's own audit findings, that duplicate discounts are far rarer than the industry asserts.

254. HRSA instead chose to take the drug industry's "word for it." *Susquehanna*, 866 F.3d at 447. It accepted the drug industry's figures uncritically, without demanding the industry's methodology or underlying data. This is precisely the "unquestioning reliance" on interested parties that courts find arbitrary and capricious. *Id.*; *Bus. Roundtable*, 647 F.3d at 1150–51. But "an agency cannot ignore evidence that undercuts its judgment; and it may not minimize such evidence without adequate explanation." *Genuine Parts*, 890 F.3d at 312. HRSA's "[c]onclusory explanations for matters involving a central factual dispute where there is considerable evidence in conflict do not suffice" under the APA. *Id.* (citation omitted).

255. Even on HRSA's own meager support for the frequency of duplicate discounts, the Program's benefits cannot outweigh the costs it imposes on covered entities. HRSA itself stated that "the included products represent less than 5.5% of total 340B sales with the remaining 94.5% of drug sales continuing under the upfront 340B discount model in 2027." 91 Fed. Reg. at 48,893. (That figure is even lower since only 18 drugs, not 25, have been approved to date.) But at the same time, the Notice attempts to quantify benefits based on duplicate discounts that purportedly occur across *the entire 340B Program*. This mixing of "apples and oranges" reflects precisely the kind 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 (5th Cir. 2018).

256. In reality, the Rebate Program will have, at most, a fractional impact on that overall figure because it includes only, at maximum, 25 drugs. Indeed, the Notice makes no assertion, nor has HRSA ever suggested, that the products responsible for this 5.5% of sales disproportionately account for a larger proportion of duplicate claims. Accordingly, even assuming that duplicate discounts "amounted to as much as $1.5 billion annually," the only specific dollar figure the Notice ever assigns to the scale of duplicated discounts, 91 Fed. Reg. at 48,887, it is clear that the benefits of the Rebate Program will be dwarfed by its costs: 5.5% of $1.5 billion would net $82.5 million in deduplication benefits annually.

257. To put it another way, if HRSA is going to rely on a figure for duplicate discounts across the entire 340B Program, it must also rely on a cost figure for the entire 340B Program. Numerous commenters explained how the costs of the program would skyrocket as more drugs are added. Given that reality, and the basic commonsense principle that costs will increase as more drugs are included, it is unreasonable to assume that adding 95% more drugs to the Program would add no costs. Yet that is what HRSA's mismatched analysis does by comparing the alleged $1.5 billion in duplicate discounts for *many thousands of drugs* in the full 340B Program to (at least) $537 million in submission costs for *just 25 drugs* in the Rebate Program. Thus, HRSA "inconsistently and opportunistically framed the costs and benefits" of the Program and violated the APA. *Bus. Roundtable*, 647 F.3d at 1148–49.

258. HRSA also did not explain how the Rebate Program itself will halt Medicaid duplicate discounts. Specifically, the Notice prohibits drug companies from denying rebates based on diversion or Medicaid duplicate discount concerns, 91 Fed. Reg. at 48,903, so the Rebate Program itself will not actually prevent a single duplicate discount or diversion. Indeed, HRSA emphasized that drug companies must use *existing* statutory audit and administrative dispute

resolution mechanisms to address duplicate discount concerns. *Id*. Accordingly, HRSA has failed to recognize that the Rebate Program itself adds few *incremental* benefits in stopping duplicate discounts because drug companies still must rely on "retrospective" statutory enforcement mechanisms that already exist.

259. In emphasizing the purported benefits of "prospective" enforcement, HRSA nowhere acknowledged its own longstanding positions that "[a] manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions," Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,113–14 (May 13, 1994), and that drug companies must continue selling at the statutory price even while an authorized audit is pending, *Or. Health & Sci. Univ. v. Engels*, 2025 WL 1707630, at *3 (D.D.C. June 17, 2025) (citation omitted). An agency may not depart from its own rules *sub silentio*. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016). Yet HRSA did so here by adopting its so-called "prospective" enforcement approach without any lawful "prospective" ability to deny duplicate discounts. Commenters correctly explained this legal barrier, but these comments went unaddressed.

260. The only asserted benefit discussed in the Notice that conceivably remains is "testing" for testing's sake, *i.e*., learning "whether rebates are an efficient means of effectuating the 340B ceiling price," 91 Fed. Reg. at 48,890. That, too, fails as a matter of law. Testing is not a benefit on its own; it is a description of the action an agency is taking. And even if it qualified as a benefit, HRSA never quantified it. HRSA's bare assertion that the testing benefits outweigh the costs, *id.* at 48,894, once again "smacks of 'clairvoyance' rather than the kind of 'exercise in logic' deserving of judicial deference." *AHA I*, 820 F. Supp. 3d at 45 (quoting *Fox*, 556 U.S. at 521).

261. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of the APA.

COUNT IV — ADMINISTRATIVE PROCEDURE ACT
(Rebate Program Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law — Failure to Adequately Consider Obvious and Less Burdensome Alternatives)

262. Plaintiffs repeat, re-allege, and incorporate all allegations in preceding paragraphs.

263. Defendants' establishment and January 1, 2027 implementation of the revised 340B Rebate Model Pilot Program, and their approval of drug company plans to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

264. An agency acts arbitrarily when it "fail[s] to consider 'significant and viable and obvious alternatives.'" *Dist. Hosp. Partners v. Burwell*, 786 F.3d 46, 59 (D.C. Cir. 2015) (quoting *Nat'l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 215 (D.C. Cir. 2013)); *Massachusetts v. HHS*, 513 F. Supp. 3d 215, 225 (D. Mass. 2021) (agency must consider "significant and viable and obvious alternatives" (internal quotation marks and citations omitted)); *Massachusetts v. Dep't of Educ.*, 828 F. Supp. 3d 198, 216 (D. Mass. 2026) (agency "must consider and explain its rejection of . . . significant and viable and obvious alternatives" (internal quotation marks and citations omitted)); *Stauffer v. IRS*, 285 F. Supp. 3d 474, 484 (D. Mass. 2017) (agency "must have a reasoned explanation for rejecting the 'reasonably obvious alternatives' available to it").

265. Although the 2026 Notice, unlike its predecessor, purports to address alternatives, its rejection of those alternatives is conclusory, circular, conjectural, and contradicted by Defendants' own concurrent conduct with the CMS clearinghouse. This amounts to a failure to engage in any meaningful consideration of those alternatives. *See Int'l Union, United Mine*

Workers, 626 F.3d at 94; *Lilliputian Sys., Inc. v. Pipeline & Hazardous Materials Safety Admin.*, 741 F.3d 1309, 1313–14 (D.C. Cir. 2014).

266. *First*, two of the alternatives that the AHA and other commenters pressed most directly are absent from the Notice: (1) the proposal that drug companies prospectively publish both the 340B price and the maximum fair price, allowing covered entities to purchase at the lower of the two and to submit limited claims data to the existing MTF for verification and reconciliation, obviating the need for any rebate; and (2) the proposal that the drug companies be required to fund participating covered entities' costs (the Notice shifted only some IT platform costs to manufacturers and never addressed the balance). Each of these alternatives would have preserved covered entities' decades of settled reliance on upfront discounts while fully serving the agency's deduplication objective. The Notice nowhere evaluates them.

267. *Second*, HRSA's rejection of four "alternatives considered" is unsupported and unreasonable. The Notice acknowledges four general categories of alternatives, requests for (1) enhanced use of claims modifiers; (2) a centralized clearinghouse; (3) more intensive audits and oversight; and (4) narrower pilot structures. HRSA then rejected all four with inadequate, illogical, or illusory analysis. 91 Fed. Reg. at 48,899.

a. **Narrower Pilot Structures.** The Notice rejects all proposals to narrow the Pilot, including fewer drugs, voluntary participation on behalf of the entities, entity-type limits, or exclusion of physician-administered drugs and contract pharmacies. HRSA did so because, in its view, a "narrowly tailored or self-selected participant pool" "could introduce substantial selection bias and reduce the reliability and generalizability of Pilot findings," and that the duplicate discount risk "attaches to particular drugs . . . rather than to particular categories

of covered entities." *Id.* at 48,901. HRSA never asked whether a representative pool would volunteer, as the AHA urged; it just speculated about the possible pool. Nor did it consider whether it could evaluate a rebate mechanism notwithstanding an imperfectly representative pool, which is exactly what pilot programs do all the time. And, in general, its rationale subordinates the concrete, documented harms of a mandatory nationwide program to the statistical purity of an "evaluation" whose objectives, metrics, and success criteria the Notice never defines. HRSA's explanation is even more unreasonable given that, in approving specific rebate plans submitted by the ten drug companies, it empowered the drug companies to exempt covered entities due to various hardships. This inconsistent treatment underscores HRSA's arbitrariness.

b. **The neutral clearinghouse.** HRSA rejected a clearinghouse as "not explicitly authorized under the 340B statute," *id.* at 48,900, without explaining or justifying that legal conclusion, despite commenters' express requests for HRSA to do so. *See supra* ¶¶ 119, 176. HRSA's legal conclusion, moreover, cannot be squared with HHS's own Medicare Part D Claims Data 340B Repository, which CMS opened to covered entities in October 2026 and has proposed to make mandatory for 2028. An agency's decision based on the "conclusory assertion that its hands were tied" is arbitrary. *Cigar Ass'n of Am. v. FDA*, 480 F. Supp. 3d 256, 279 (D.D.C. 2020). Likewise, HRSA's reliance on covered entities' purported "incentives" to comply with a rebate mechanism

is speculative, illogical, and contrary to the administrative record. *See supra* ¶¶ 177–79 & n.9.

c. **More intensive audits and oversight.** The third alternative that HRSA listed received no individualized engagement. Despite identifying "more intensive audits and oversight activities" as a distinct alternative proposal, 91 Fed. Reg. at 48,899, the Notice never returns to it. Its only response is the generic assertion that "[r]etrospective reviews, audits, and dispute resolution processes are inherently reactive, identifying potential duplicate discounts only after they have occurred." *Id.* at 48,901. That is not consideration; it is a description or, at best, a circular argument that because audits and oversight are not a rebate mechanism, they are not a valid alternative to one.

d. **Claims modifiers.** The Notice rejects "enhanced use of claims modifiers" because oversight reports have criticized the Medicaid Exclusion File, which "relies on claims modifiers as its central mechanism," and because modifiers "can be applied inconsistently, may be incomplete or unavailable at the time of adjudication, and depend on voluntary compliance." *Id.* at 48,899–900. But that answers a proposal no one made. Commenters did not defend the *existing* Medicaid Exclusion File; they proposed enhancing the modifier system by standardizing identifiers, extending them to Medicaid managed care, and pairing them with the data-sharing arrangements the Notice itself acknowledges commenters proposed, *id.* at 48,890, but never separately addresses.

268. *Third*, the Notice dismisses *any* alternative that preserves upfront discounts on grounds that such an alternative "would not inform whether rebates are an efficient means of

effectuating the 340B ceiling price . . . and therefore would fail to advance the central purpose of the Pilot." *Id.* at 48,890. But that rationale is, again, circular: the alternatives to a rebate mechanism are inadequate because they are not a rebate mechanism. An agency cannot define its objective as the action itself and then reject every alternative for failing to be that action. *See Am. Pub. Health Ass'n v. Nat'l Insts. of Health*, 145 F.4th 39, 54 (1st Cir. 2025) (describing "circular reasoning" as a "hallmark[] of arbitrary and capricious decision-making"); *Firearms Regul. Accountability Coal., Inc. v. Garland,* 112 F.4th 507, 523–24 (8th Cir. 2024) (finding agency action to be arbitrary and capricious where it "relie[d] on circular reasoning").

269. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of the APA.

COUNT V — ADMINISTRATIVE PROCEDURE ACT
(Rebate Program Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law — Failure to Consider Serious Reliance Interests)

270. Plaintiffs repeat, re-allege, and incorporate all allegations in preceding paragraphs.

271. Defendants' establishment and January 1, 2027 implementation of the revised 340B Rebate Model Pilot Program, and their approval of drug company plans to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

272. An agency must "assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *Regents*, 591 U.S. at 33; *see Doe v. Noem*, 152 F.4th 272, 290 (1st Cir. 2025). And where its prior policy "has engendered serious reliance interests," it must provide "a more detailed justification." *Fox*, 556 U.S. at 515; *Encino Motorcars*, 579 U.S. at 222, 224 ("conclusory statements do not suffice" in light of "decades of industry reliance"). "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." *AHA I*, 820 F. Supp. 3d at 42 (citing *Fox,* 556 U.S. at 515–16, and *Smiley v. Citibank (S.D.), N.A.*, 517 U.S. 735, 742 (1996)); *see AHA II*, 164 F.4th at 33 (reliance interests are "a critical factor in the analysis of an arbitrary-and-capricious claim").

273. Defendants' treatment of reliance interests fails these requirements. Having conceded in the prior litigation that covered entities' three decades of reliance on upfront discounts is significant—a concession credited by this Court and the First Circuit—Defendants have now declared that "exclusive reliance on an upfront discount model" was never reasonable "as a matter of law" because the statute authorizes rebates for some covered entities and because a separate federal program uses rebates. 91 Fed. Reg. at 48,888–89. In HRSA's view, covered entities *never* should have relied on HHS's consistent thirty-plus-year practice because the agency always had the discretion to change course.

274. That is not weighing reliance; it is defining it away. Courts have rejected similar efforts. *See Regents*, 591 U.S. at 31–32 (rejecting the argument that an agency "does not need to" consider reliance interests where a policy "conferred no substantive rights," provided benefits only in two-year increments, and was revocable at the agency's discretion); *Texas v. Biden*, 20 F.4th 928, 989–91 (5th Cir. 2021) (observing that in *Regents* the Supreme Court acknowledged that DACA was a discretionary program but DHS had still unlawfully failed to consider reliance interests), *rev'd and remanded on other grounds*, *Biden v. Texas*, 597 U.S. 785 (2022); *Centro Legal de la Raza v. EOIR*, 524 F. Supp. 3d 919, 971 (N.D. Cal. 2021) ("The government's contention that the agency was free to dismiss any reliance interests because there is no right to discretionary *sua sponte* reopening is akin to the government's losing argument in *Regents* . . . ."); *Am. Fed'n of Gov't Emps. v. U.S. Fed. Lab. Rels. Auth.*, 2026 WL 1870987, at *11 (D.

Mass. June 29, 2026) ("In both *Centro Legal* and *Regents*, the courts concluded that the fact that reliance interests in a prior rule did not stem from a vested right granted by said rule did not absolve the agency of the need to consider reliance interests."). Indeed, the First Circuit recently applied *Regents* in rejecting the government's argument that it need not weigh reliance interests where the underlying grants "allow for termination in certain circumstances." *Woonasquatucket River*, 186 F.4th at 46–47 (agencies "acted arbitrarily and capriciously by failing to consider reliance interests"). Just because a framework allows for the "foreseeable" changes in circumstances does not make reliance on thirty years of prior practice and policy any less reasonable.

275. Here, the covered entities' reliance rests on decades of unbroken agency practice, HRSA's published guidance confining rebates to ADAPs, and the agency's own representations (in *Federal Register* notices, letters to manufacturers, and federal court filings as recently as 2025) that upfront discounts are the preferred and superior payment mechanism. The Notice confronts none of this history and relies principally on the fact that the decision to authorize an upfront discount mechanism was discretionary. But "particular[ly] because of decades of industry reliance on the Department's prior policy," *Encino Motorcars*, 579 U.S. at 222, HRSA was required to offer more than its blithe explanation ("you should know we can change our minds at any time") for dismissing covered entities' reliance interests.

276. HRSA's reliance analysis also erects a straw man, writing: "But even if one assumed for the sake of discussion that covered entities' reliance interests in this context are reasonable as a matter of law, such a conclusion does not thereby transform such reliance interests into a categorical prohibition against the Secretary exercising his express statutory discretion to provide for 340B pricing via 'rebate or discount.'" 91 Fed. Reg. at 48,889. No stakeholder makes those arguments. Rather, the reliance interest was generated by HRSA's consistent adherence to,

and affirmative endorsement of, the upfront-discount mechanism. The more that happened, the more reasonably covered entities could expect HRSA not to abandon that approach and structure their operations and investments around it. Put differently, despite HRSA always having had the *discretion* to switch to a rebate mechanism, covered entities had ample basis, based on HRSA's own words and deeds, to "buil[d] up decades of reliance" on the upfront discount mechanism. *Wages & White Lion Invs.*, 604 U.S. at 585. HRSA discussed none of those words or deeds, and it thus failed to provide the "more detailed justification" required here. *Fox*, 556 U.S. at 515.

277. Further, contrary to HRSA's contention, 91 Fed. Reg. at 48,888, the use of rebates in other federal programs does not diminish covered entities' reliance on thirty-three years of the upfront discount mechanism in *this* federal program. Medicare Part D, which the Notice highlights as relying extensively on rebates, is a separate program for a non-identical set of purchasers and drugs. And Medicare Part D is fundamentally different from 340B in mechanics and purpose. The use of a rebate program in this altogether different context does not diminish the reliance interests of covered entities in this context.

278. HRSA's fallback argument also fails. In a single paragraph of analysis, the agency insisted that any reliance interests are "on balance" outweighed by "the significant benefits of proceeding with the Pilot as described in this Notice." *Id.* at 48,889. But HRSA has not reasonably calculated those benefits, making it impossible for those purported "benefits" to reasonably outweigh any reliance interests. *See supra* ¶¶ 138–43, 252–57. HRSA's conclusory statement that it "has taken into consideration covered entities' reliance interests" and found that they do not outweigh the benefits of the Program, 91 Fed. Reg. at 48,889, also does not adequately assess reliance interests. *See AHA I*, 820 F. Supp. 3d at 42 ("It is arbitrary and capricious to ignore the facts and circumstances engendered by that prior policy."). On *both* sides of the balance, HRSA

did not conduct a rational weighing of the reliance interests and purported benefits. And at a minimum, this again is not the "more detailed justification" required under these circumstances. *Fox*, 556 U.S. at 515.

279. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of the APA.

COUNT VI — ADMINISTRATIVE PROCEDURE ACT
(Rebate Program Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law — Failure to Consider Important Aspects of the Problem)

280. Plaintiffs repeat, re-allege, and incorporate all allegations in preceding paragraphs.

281. Defendants' establishment and January 1, 2027 implementation of the revised 340B Rebate Model Pilot Program, and their approval of drug company plans to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

282. Defendants failed to consider other important aspects of the problem squarely presented in the comments. *State Farm*, 463 U.S. at 43; *Ohio v. EPA*, 603 U.S. at 293–94.

283. The starkest failure is HRSA's silence about the financial environment confronting safety-net hospitals, including the OBBBA's "historic $1 trillion cut" from Medicaid and Marketplace spending. The AHA and others expressly told Defendants that this is an important aspect of the problem they were obligated to confront. They explained that these pressures "will hit many of America's 340B hospitals the hardest because they treat large Medicaid populations while operating . . . on the thinnest of margins," and that HRSA "must provide a reasoned explanation for imposing the costs of the Rebate Program *on top of* the costs of the OBBBA and other developments." AHA Letter at 37–38 (emphasis in original); *see also* HRSA-2026-0001-1783 at 2–3; HRSA-2026-0001-1994 at 5. The Notice offers no explanation at all.

284. While Defendants failed to consider myriad other important aspects of the problem, two additional failures loom particularly large:

a. **Vendor Problems**: Defendants failed to confront the documented failures of the drug-company-selected vendor platforms on which the entire Pilot depends. Covered entities raised concrete, quantified evidence from their 2026 experience under the Medicare Drug Price Negotiation Program: misclassified claims, false denials, and payment delays running months past the applicable window, described *supra* ¶¶ 99, 130–32, 158. Instead of engaging with the evidence of significant issues that plagued the 2026 MFP platforms, HRSA parroted statements from Second Sight Solutions' comment letter, uncritically crediting the vendor's self-interested assertions. 91 Fed. Reg. at 48,891–94.

b. **Dispute Resolution:** The administrative record showed that a workable, impartial process for resolving rebate delays and denials is an essential prerequisite to any rebate mechanism. Without HRSA's active role, "there is little hope that disputes will actually get resolved," and drug companies will be affirmatively incentivized to delay and deny. AHA Letter at 51. The AHA asked for a designated point of contact, a specified procedure, decisions within thirty days, and a denial form requiring a narrative explanation, primary-source support, and an attestation. *Id.* at 51–52 & nn.50–52; *see also* HRSA-2026-0001-1914 at 13–16 (comment of AAMC). The Notice and follow-up FAQs identify no decisionmaker, prescribe no procedure, set no deadline, and provide no remedy; the Notice defers reporting "tools" until after the Pilot begins, offers only a discretionary "could review a sample" construct, and otherwise relegates

covered entities to an administrative dispute resolution process whose backlog means disputes would outlast the one-year "pilot" itself. 91 Fed. Reg. at 48,895–96, 48,903.

285. As to each of these problems, the Notice either says nothing or offers a response that runs counter to the evidence before the agency. *State Farm*, 463 U.S. at 43.

286. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of the APA.

COUNT VII — ADMINISTRATIVE PROCEDURE ACT
(Rebate Program Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law — Predetermined Result)

287. Plaintiffs repeat, re-allege, and incorporate all allegations in preceding paragraphs.

288. Defendants' establishment and January 1, 2027 implementation of the revised 340B Rebate Model Pilot Program, and their approval of drug company plans to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

289. An agency acts unlawfully when it is "unwilling or unable to rationally consider counterarguments" because it has committed to a predetermined result. *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. v. New York*, 588 U.S. 752 (2019); *see Kravitz v. U.S. Dep't of Com.*, 366 F. Supp. 3d 681, 750 (D. Md. 2019); *Davis v. Mineta*, 302 F.3d 1104, 1112–13 (10th Cir. 2002).

290. Courts closely scrutinize an agency that, after judicial rejection of its position, arrives at the same result. In those circumstances, the agency's action "must be more than a barren exercise of supplying reasons to support a pre-ordained result," *Food Mktg. Inst. v. ICC*, 587 F.2d 1285, 1290 (D.C. Cir. 1978); *see Greyhound Corp.*, 668 F.2d at 1358; *Wint*, 902 F.2d at 81; *Regents*, 591 U.S. at 21 (an agency's post-remand explanation "must be viewed critically to ensure

that the action is not upheld by the court on the basis of impermissible post hoc rationalization" (cleaned up)).

291. *First*, Defendants' conduct following the dismissal of the prior action proves their commitment to a predetermined outcome. Despite receiving more than 4,000 total comments across the 2025 Notice, the 2025 ICR, the 2026 RFI, the February 2026 ICR, and the June 2026 ICR, HRSA has not deviated in any meaningful way from its predetermined conclusion to forge ahead with a rebate mechanism. After issuing an RFI just days after its original Rebate Program was vacated, the agency adopted the same rebate mechanism architecture, the same mandatory nationwide scope, the same erroneous 10-day payment premise, and the same reliance on manufacturer-selected platforms, while *expanding* the program from ten drugs to 18 (with more to possibly come) and avoiding any firm end date for its purported "pilot."

292. *Second*, at every disputed factual juncture, the agency credited the drug companies' and their vendors' conclusory assertions over the detailed, firsthand evidence of the entities the statute protects. Indeed, "after this Court enjoined [HRSA's] original [Rebate Program] . . . , the agency 'cherry-picked' materials to support the same predetermined policy choice." *Kingdom v. Trump*, 2026 WL 1746251, at *12 (D.D.C. June 17, 2026) (quoting *Afr. Communities Together v. Noem*, 820 F. Supp. 3d 48, 67 (D. Mass. 2026), *rev'd and remanded on other grounds sub nom. Afr. Communities Together v. Mullin,* 183 F.4th 77 (1st Cir. 2026)). HRSA *always* took the word of those who supported its predetermined result, even though covered entities are best situated to assess what the on-the-ground costs of this proposed program will be and regardless of how flimsy the contrary evidence (*e.g.*, the IQVIA study, 2019 estimates of duplicate discounts, etc.) was. In fact, although courts and Plaintiffs use "word" in the metaphorical sense when they say HRSA took the drug industry's "word" for it, *see Susquehanna*, 866 F.3d at 447, here, it is literally true.

In many instances, HRSA used *exactly the same text* as drug companies or their trade association without ever attributing that language or critically assessing it in the face of contrary evidence. *See supra* ¶ 178.

293. *Third*, HHS officials engaged in *ex parte* communications with drug companies prior to the 2025 Rebate Program and, on information and belief, thereafter. The drug companies attached documentation to their litigation filings in the prior litigation citing some of these communications. *See, e.g.*, *Am. Hosp. Ass'n v. Kennedy*, No. 2:25-cv-600 (D. Me.), Dkt. Nos. 85, 85-2, 85-3, 88, 88-1. Plaintiffs do not know the substance or extent of these private conversations, but their closed-door nature raises serious concerns about HRSA's willingness "to rationally consider counterarguments" from covered entities. *New York v. U.S. Dep't of Com.*, 351 F. Supp. 3d at 663.

294. *Fourth,* many stakeholders asked HRSA to provide a further opportunity for comment on the specifics of any new program because the RFI proposed no concrete design on which meaningful comment was possible. *See* AHA Letter at 53; HRSA-2026-0001-1914 at 4 (without the parameters of a potential rebate mechanism, "it is impossible to accurately provide the information HRSA is looking for"). HRSA never responded to that request in the Notice, and in fact wrongly faulted covered entities for not considering certain programmatic design features when submitting their cost estimates. HRSA instead announced a completed program, effective immediately upon publication, with manufacturer plan approvals to quickly follow within seven weeks. It appears that HRSA did this because it wanted to initiate its Rebate Program by January 1, 2027, but its agreement with Plaintiffs required the agency to provide 90 days of lead time before implementation. Joint Motion for Vacatur and Remand at 4, *Am. Hosp. Ass'n v. Kennedy*, No. 2:25-cv-600 (D. Me. Feb. 5, 2026), Dkt. No. 114. Thus, not only was HRSA committed to moving

forward with its predetermined Rebate Program, but it was also committed to doing so by a predetermined date, regardless of (1) whether its ICR/cost analysis was complete; (2) whether it was ready to announce a dispute-resolution process (*see supra* ¶¶ 166–68, 186(b)); and (3) whether an additional round of comments would have informed its decision about key design elements of the Program.

295. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of the APA.

Prayer for Relief

Wherefore, Plaintiffs respectfully request that this Court declare that HRSA's approvals of drug company plans under the 340B Rebate Model Pilot Program are unlawful; "set aside" the 340B Rebate Model Pilot Program and the approvals under 5 U.S.C. § 706(2)(A); and award any other relief the Court deems necessary and just, including as appropriate using its equitable powers to enter orders providing:

A. The Rebate Program and HRSA's approvals of the drug companies' plans are permanently enjoined as unlawful and invalid;

B. Defendants are enjoined from implementing or giving effect to the Rebate Program in any way, including by approving drug company plans; and

C. Defendants are directed to rescind any and all statements, guidance, or direction already issued relating to announcing, implementing, or enforcing the Program, including Frequently Asked Questions, as they pertain to the Rebate Program.

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Respectfully submitted,

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**Pro hac vice application forthcoming.*