UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MAINE

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

Introduction

1. More than thirty 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," this law allows these healthcare providers to purchase certain outpatient medications at reduced cost and use the savings to expand 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 inception of the 340B Program, the Health Resources and Services Administration ("HRSA")—the agency of the U.S. Department of Health and Human Services ("HHS") tasked with administering the 340B Program—has required drug manufacturers to offer discounted medications at the time of the sale rather than as a delayed rebate. This is known as an "upfront discount." Many covered entities that participate in the 340B Program operate on razor-thin (or negative) margins and cannot afford the costs of paying market prices for drugs (which are multiples of the 340B price) without sacrificing the care they provide to patients. Implementing the 340B Program via "upfront discounts" honors the purpose of the statute by enabling healthcare providers to stretch scarce federal resources as far as possible to provide greater access to care for the patients and communities they serve.

3. For years, drug companies have sought to move from an "upfront discount" model to what they call a "rebate" model. Under this approach, safety-net providers would be forced to

initially pay drug companies full market price and then seek reimbursement for the discounted difference after administering the drugs to patients and providing detailed claims data to drug companies. Such a change would inflict hundreds of millions of dollars' worth of annual costs on hospitals and other covered entities. *First*, a rebate system would impose vast administrative costs to submit, track, recover, and potentially dispute the rebates. *Second*, it would drain 340B hospitals of huge sums of money through payments to drug companies that the hospitals then must wait to have refunded by those drug companies. *Third*, a rebate system would invite mischief from drug companies that have every incentive to slow and stymie the issuance of rebates, figuring that some number of rebates can be withheld from safety-net hospitals by throwing the proverbial "sand in the gears."

4. For these reasons, the 340B Program has operated under the "upfront discount" model for more than 30 years. They are why HRSA has refused drug companies' repeated efforts to switch to a "rebate" program. They are why HRSA has, for decades, pointed to the benefits of the "upfront discount" model and the shortcomings of a "rebate" program. And they are why HRSA reiterated those very costs and benefits in repeated federal court filings *this year*.

5. But, without any warning to 340B hospitals or other covered entities, HRSA has suddenly reversed course. This summer, the agency announced that it was commencing a "340B Rebate Model Pilot Program" (hereinafter "Rebate Program") that would institute a rebate model for a swath of popular drugs. HRSA acknowledged that "rebate models could fundamentally shift how the 340B Program has operated for over 30 years[.]" 90 Fed. Reg. 36163, 36164. Yet it proceeded to ignore the reasons behind its historic skepticism of the rebate model; it failed to explain its change in position or clarify its rationale for the new program; and it failed to account for thirty-plus years of reliance interests on the part of covered entities.

6. HRSA announced this mandatory Rebate Program with manifest disregard for the tremendous costs it will impose upon the most vulnerable covered entities—costs that HRSA recognizes in internal government documents will total hundreds of millions of dollars per year. Astonishingly, when explaining its new Rebate Program, HRSA has not even acknowledged its own longstanding concerns about the massive costs of forcing a rebate model on safety-net providers. Its public discussion, including a notice published in the Federal Register and details posted to a government website, are entirely silent on the subject of costs. HRSA has given no public explanation of what it believes the costs are, what the benefits of the Rebate Program are, or why it is necessary to place those costs on the intended beneficiaries of the 340B Program—safety net healthcare providers that serve America's most vulnerable patients.

7. The newly announced Rebate Program is a "pilot" in name only. Rather than starting in a more circumscribed fashion, as is customary for any true pilot program, it applies to *every* 340B hospital and covered entity in America—approximately 14,600 entities by HRSA's own estimate. Participation is *compulsory* for those covered entities; they are *required* to participate or lose their statutorily-owed discounts. By contrast, drug companies have the *option* of applying to participate. Likewise, the drugs covered by HRSA's new Rebate Program are among the most commonly prescribed in the country, meaning that the costs of including these drugs in the Rebate Program will be especially high.

8. HRSA's surprise announcement garnered more than 1,100 comments from stakeholders raising concerns about the Rebate Program. Commenters identified a slew of important issues, including: (a) the costs that HRSA failed to address or balance against any purported benefits of the program; (b) less burdensome alternatives that would achieve HRSA's stated goals; (c) serious concerns about HRSA's chosen software platform, "Beacon," that have

since proven to be prescient; (d) problems with an underdeveloped mechanism for resolving disputes between drug companies and covered entities; and (e) the difficulties that struggling safety-net hospitals will face in standing up this program by the January 1, 2026 effective date.

9. HRSA ignored those comments. It did not, as the law requires, address "important problem[s] the public could and did raise during the comment period." *Ohio v. EPA*, 603 U.S. 279, 298 (2024). And having offered no response at all, HRSA necessarily did not, as the law requires, offer a "*reasoned* response." *Id.* at 293 (emphasis added).

10. Instead, on October 15, 2025, HRSA confirmed that the new program would commence on January 1, 2026—giving hospitals only two months to comply or risk losing millions of dollars in discounts they are entitled to under the 340B statute. Since then, HRSA has been largely absent as covered entities await further guidance on how the program will work in practice. Indeed, on information and belief, HRSA has not even bothered to test the software platform on which this program is supposed to run—just one more example of the lack of careful consideration that has gone into this transformative decision.

11. HRSA's "340B Rebate Model Pilot Program" is a textbook disregard of administrative law. HRSA has failed to grapple with the key problems of a rebate model that the *agency itself* flagged for years—again, as recently as this year. HRSA has ignored the thousand-plus comments from 340B hospitals and other stakeholders, including comments that identified "important aspect[s] of the problem" like the massive costs of standing up and administering the rebate model. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.,* 463 U.S. 29, 43, 52 (1983). HRSA has never balanced those costs against the limited benefits of its Rebate Program "pilot." HRSA has never addressed 340B providers' strong reliance interests, including that they have built entire internal operations around the upfront discount model and rely on the

benefits of that model to provide more comprehensive care to patients. HRSA has not explained why a nationwide mandate on all covered entities is necessary for its so-called "pilot" program, rather than narrower and less costly alternatives. And HRSA ignored comments explaining that a delayed effective date would allow covered entities to better prepare for what HRSA itself recognized is a "fundamental[] shift" in how the 340B Program will operate.

12. Thousands of 340B hospitals and other 340B providers will face crushing costs and consequences should the Rebate Program go into effect as intended on January 1, 2026. That, in turn, will jeopardize their ability to provide care to 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 healthcare to their patients, this Court must quickly enjoin this unlawful, unnecessary, unexplained, and substantively unreasonable program that jeopardizes one of the key pillars of U.S. healthcare—the 340B Program.

Parties

13. Plaintiff American Hospital Association ("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 St. Mary's Regional 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, 2026 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.

14. Plaintiff Maine Hospital Association (MHA) is a nonprofit association that represents 32 community-governed hospitals in Maine. Its principal place of business is Augusta, Maine. MHA represents its members, including St. Mary's Health System, 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, 2026 effective date. Protecting those members' interests is germane to MHA's organizational purpose of supporting its members in improving the health of their patients and the communities they serve, and the individual members' participation is not required to adjudicate the claims for relief.

15. Plaintiff St. Mary's Regional Medical Center is a 501(c)(3) nonprofit health system comprised of an acute care community hospital, a professional provider network of specialists and primary care providers, urgent care, an emergency department, and a broad spectrum of behavioral health services. It strives to provide patients with convenient access to high quality, compassionate care throughout Androscoggin County, Maine. St. Mary's principal place of business is in Lewiston, Maine. St. Mary's 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.

16. 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.

17. 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 that Rebate Program.

18. 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 that Rebate Program.

Defendants

19. 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.

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

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

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

23. 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

24. This action arises under, and asserts violations of, the Administrative Procedure Act ("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.

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

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

27. 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).

28. The Rebate Program reflects the consummation of the agency's decision-making process. HRSA has approved drug company rebate plans for a total of ten drugs, all but one of which will take effect on January 1, 2026. That creates real-world consequences for Plaintiffs, their members, and other covered entities. They must either proceed to 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.

29. HRSA's establishment and implementation of the 340B Rebate Model Pilot Program, as well as its approval of 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

30. Congress created the 340B Drug Pricing Program in 1992 to give safety-net healthcare providers a financial lifeline by allowing them to purchase drugs at discounted prices. When it was enacted, Congress stated that the program's 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); *see also Novartis Pharms. Corp. v. Frey*, 1:25-cv-00407, 2025 WL 2813787, at *9 (D. Me. Sep. 23, 2025) ("The 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, entities providing outpatient early intervention services for HIV, state-operated AIDS drug assistance programs, black lung clinics, hemophilia diagnostic treatment centers, Native Hawaiian health centers, 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).

31. 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 providers through the 340B Program, Medicaid and Medicare Part B will not cover the companies' drugs. *Id.* § 1396r-8(a)(1).

32. The 340B Program plays a critical role in 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 2023, more than 2,600 hospitals participated in the 340B Program.

33. For Plaintiffs like St. Mary's, Nathan Littauer Hospital, Unity Medical Center, and Dallas County Medical Center, the 340B Program is necessary to their mission and survival. For example, in 2025, the 340B Program will provide approximately $3.3 million in savings to St. Mary's, which has not had a positive operating margin since before the COVID-19 pandemic and is projecting a substantial operating loss this year. The 340B Program provides approximately $1.1 million to Dallas County Medical Center each year. Without that money, Dallas County Medical Center could not maintain its hospital, equipment, and staffing levels, leaving the approximately 3,400 residents of Fordyce, Arkansas, and the surrounding area, 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 Model

34. 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).

35. 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 takes into account 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. 27289, 27291 (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).

36. Since the beginning of the 340B Program, HRSA has required drug companies to offer upfront discounts—not rebates—to covered entities. *See* 42 U.S.C. § 256b(a)(1); 58 Fed. Reg. at 27291–92. Upfront discounts work as follows: a covered entity makes an initial purchase of drugs at wholesale cost. The covered entity then dispenses drugs from that initial purchase to both 340B eligible and non-eligible patients. A third-party evaluates the claims data to determine how many units were dispensed to a 340B eligible patient. After the covered entity has dispensed enough 340B eligible units of a particular drug to equal the number of units in the drug's package, the covered entity may purchase subsequent packages of those drugs from the manufacturer at a 340B-discounted price. As a result, other than a first-time purchase at full price, 340B providers almost always pay only the discounted price.

37. The single narrow exception to the upfront discount model is for drugs sold to a certain category of covered entities to which none of Plaintiffs belong: AIDS Drug Assistance

Programs ("ADAPs"). HRSA determined that rebates were an appropriate mechanism to effectuate price reductions for ADAPs because ADAPs had drug purchasing systems that largely prevented their participation in the section 340B discount program. Specifically, before 1998, covered entities could only work with one pharmacy to make drug purchases, regardless of whether that pharmacy was in-house or contracted. As a result, a significant number of ADAPs did not participate in the 340B Program, which led to HRSA "recogniz[ing] rebates obtained by the State ADAPs that equal or exceed the discount provided by the statutory ceiling price as a method of accessing the 340B Program." 62 Fed. Reg. 45823, 45824. But even when HRSA approved rebates as a permissible mechanism for ADAPs, the agency declined to authorize manufacturers to pay rebates to all other covered entities. HRSA specifically found that "the [upfront] discount system is *functioning successfully for most covered entities*[.]" 62 Fed. Reg. at 45824 (emphasis added). In any event, rebate purchases from ADAPs made up less than *$43 thousand* of all *$66.3 billion* in 340B Program purchases in 2023, the most recent year for which HRSA has published data, so there has never been a significant rebate model imposed in the 340B context. *See* HRSA, *2023 340B Covered Entity Purchases,* https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases.

38. Covered entities often implement upfront pricing through what is known as the "product-replenishment model." Under this longstanding 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 generally Novartis Pharms. Corp.*, 2025 WL 2813787, 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).

39. This "upfront discount" model makes perfect sense given Congress's intent for the 340B Program. Rural hospitals and other 340B providers operate on thin (or negative margins) and serve vulnerable patient populations. Forcing those entities to float hundreds of millions of dollars to the drug industry each year until the drug companies decide whether and when to issue a rebate puts covered entities at existential risk and endangers the health of their patients and communities.

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

40. For years, drug companies have tried to undermine the value and efficacy of the 340B Program through proposals that would, in effect, transfer hundreds of millions of dollars from covered entities to drug companies—many of which are among the most profitable companies in the world. One such technique has been to try to deploy a rebate model for some or all drugs covered under the 340B Program, not because the administration of these drugs requires a rebate mechanism, but because this would make the drug companies more money.

41. HRSA has long taken the position that it has the authority to approve how drug companies must provide 340B discounts, including whether through an upfront discount or a rebate model. This is consistent with the 340B statute's legislative history, which states:

> The Committee bill does not specify whether "covered entities" would receive these favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism. A mechanism that is appropriate to one type of "covered entity," such as community health centers, may not be appropriate to another type, such as State AIDS drug purchasing programs. 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."*

H.R. Rep. 102-384, pt. 2, at 16 (1992) (emphasis added) (quoted in *Johnson & Johnson Health Care Sys. Inc. v. Kennedy*, 2025 WL 1783901, at *10 (D.D.C. June 27, 2025)). For years, HRSA rejected drug company efforts to impose rebate models, recognizing that they are decidedly *not* the "most effective and most efficient" mechanisms for providing discounts "from the standpoint of" 340B hospitals. *Johnson & Johnson Health Care Sys. Inc.*, 2025 WL 1783901, at *10.

42. In 2024, certain drug companies tried again to undermine the 340B Program's upfront discount model. Specifically, in mid-to-late 2024, drug companies Johnson & Johnson ("J&J"), Eli Lilly, Bristol Myers Squibb, Novartis, and Sanofi announced plans to require at least some 340B covered entities to purchase certain drugs at market prices, known as the full Wholesale Acquisition Cost ("WAC"), and then apply for a rebate after dispensing to a 340B-eligible patient. WAC is the highest cost for which a pharmaceutical company sells a drug. Despite some differences in their proposed rebate models—J&J's initial proposal was limited to two drugs, while Eli Lilly's proposed model would have applied to all of its drugs—the end result would have been the same: drug companies would have unilaterally imposed a rebate system.

43. Recognizing that the abandonment of the upfront discount model would jeopardize the goals of the 340B Program and grievously harm covered entities, HRSA promptly took action to prevent the drug companies from switching to a rebate model. For example, on August 14, 2024, HRSA sent a letter to J&J stating that "[t]his shift [to a rebate model] would disrupt how the 340B Program has operated for over thirty years. As a result of this shift, covered entities, including those which primarily serve rural and underserved populations, would need to pay significantly higher prices on prescription drugs at the time of purchase." 340B_REBATES_000064 at -66, filed in *Eli Lilly & Co. v. Kennedy*, No. 1:24-cv-03220 (D.D.C. 2024) (the "*Eli Lilly* Case"), Dkt. 60-1.

44. HRSA also warned J&J that it did not have the authority to unilaterally impose a rebate program and asked J&J a series of questions about its proposed rebate model. Notably, several of these are questions that, as discussed below, HRSA *itself* has not answered about its own pilot program. Among other things, HRSA asked:

a. Whether "J&J conducted an evaluation of the impact of this proposal on the scope and breadth of health care access for patients served by affected covered entities";

b. Whether "J&J conducted an analysis of the extent of the additional burden and/or costs to the affected covered entities, particularly those that are the sole or primary source of health care in a rural or underserved community";

c. How J&J planned to protect the claims information it collected, with whom it would share that information, and how it would "ensure such information would solely be used in support of the 340B Program";

d. On what specific grounds would J&J deny a rebate claim;

e. How J&J would adjudicate actual and potential rebate claim denials, and what appeal process would J&J put in place for denials; and

f. How J&J planned to issue refunds.

Id. at -66–68.

45. On September 17, 2024, HRSA followed up with a second letter to J&J, stating that the company risked violating the law if it implemented its rebate program. In this letter, HRSA again noted that J&J's model would impose enormous costs on hospitals and covered entities: "[U]nder the J&J proposal, covered entities would be forced to pay a higher price point up front for every purchase. This would create significantly higher up-front costs for covered entities." 340B_REBATES_000201 at -03, filed in the *Eli Lilly* Case, Dkt. 60-1. HRSA went on to note

other flaws in J&J's proposal, namely that J&J "does not commit to an enforceable timeframe for issuing the 'rebate payment,'" and that the proposal subjected rebate payments to so many conditions that "issuance of the 'rebate payment' is conditioned on J&J's prior approval at J&J's sole discretion." *Id.*

46. In its September 17, 2024 letter, HRSA went so far as to argue that any rebate program that forces a covered entity to pay more than the ceiling price, as calculated under the 340B statute, is *illegal* under federal law: "J&J intends to unilaterally charge disproportionate share hospitals 'commercial price[s], such as [WAC]' for covered outpatient drugs . . . . J&J's rebate proposal would require disproportionate share hospitals to purchase [J&J's drugs] at prices that exceed 'the maximum price[s] that covered entities may permissibly be required to pay' for those drugs. This, too, violates Section 340B(a)(1) of the [Public Health Service] Act." *Id.*

47. On September 27, 2024, HRSA sent a third letter to J&J warning that if it did not cease its proposed rebate program, HRSA would terminate J&J's participation in the 340B Program (thereby making it ineligible for Medicare and Medicaid participation) and refer J&J to the HHS Office of Inspector General. 340B_REBATES_000212 at -14, filed in the *Eli Lilly* Case, Dkt. 60-1.

48. Eli Lilly, Bristol Myers Squibb Co., Novartis Pharmaceuticals Corp., and Sanofi-Aventis U.S. LLC ("Sanofi"), all received similar letters from HRSA about their proposed rebate programs. In a September 18, 2024 letter to Eli Lilly, for example, HRSA informed Eli Lilly that its unilateral imposition of a rebate program was illegal and stated that it "would disrupt how the 340B Program has operated for over thirty years. As a result of this shift, covered entities, including those which primarily serve rural and underserved populations, would need to pay

significantly higher prices on prescription drugs at the time of purchase." 340B_REBATES_000292, filed in the *Eli Lilly* Case, Dkt. 60-1.

49. On November 12, 2024, J&J responded to HRSA's defense of the upfront discount model by filing a federal lawsuit against the same Defendants as in this case—HHS, HRSA, and the HHS Secretary and HRSA Administrator in their official capacities. *J&J Health Care Sys. Inc. v. Kennedy*, No. 24-cv-3188 (D.D.C. Nov. 12, 2024). The other drug companies followed suit soon thereafter. *Eli Lilly & Co., et al. v. Becerra*, No. 24-cv-3220 (D.D.C. Nov. 14, 2024); *Bristol Myers Squibb Co. v. Johnson*, No. 24-cv-03337 (D.D.C. Nov. 26, 2024); *Sanofi-Aventis U.S. LLC v. U.S. Dep't of Health and Human Servs.*, No. 24-cv-03496 (D.D.C. Dec. 16, 2024); *Novartis Pharms. Corp. v. Becerra*, No. 25-cv-00117 (D.D.C. Jan. 15, 2025). Collectively, the companies asked the courts to vacate HRSA's letters and declare that their rebate models were lawful under the 340B statute.

50. While defending themselves against the drug companies' lawsuits, HRSA and HHS—Defendants in the instant action—repeatedly defended the upfront discount model.

a. In their March 17, 2025 motion for summary judgment in the *Eli Lilly* litigation, Defendants noted that "widespread adoption of rebate models would cause unprecedented disruption to the program." Dkt. 35-1 at 20, the *Eli Lilly* Case, No. 24-cv-3220.

b. In their April 2, 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-03188. HRSA

and HHS noted that HRSA "was concerned that the arrangement that [J&J] proposed would 'create significantly higher up-front costs for covered entities.'" *Id.* at 19.

c. In that same motion, 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 not only the manufacturers' preferences, but also how the changes would affect the operations of covered entities and the wellbeing of patients who rely on 340B drugs, before allowing manufactures to redesign the operation of the program." *Id.* at 20.

d. In an August 1, 2025 brief filed with the D.C. Circuit, HHS and HRSA further defended the upfront discounts and flagged concerns with rebates in the 340B Program. "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.

51. The presiding federal district courts concluded that HRSA could prohibit drug companies from unilaterally imposing rebate models, explaining that covered entities would "'be forced to incur higher carrying costs for these drugs, essentially floating revenue to drug manufacturers'" and "'reduc[ing] the hospitals' resources available for other patient care.'" *Johnson & Johnson Health Care Sys. Inc.*, 2025 WL 1783901 at *12 (quoting AR 568); *see also Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630, at *12 (D.D.C. May 15, 2025) ("Most critically, a cash rebate model shifts the initial outlay for drug costs from manufacturers to covered entities. . . . Thus, the impact of a rebate float was a relevant factor the agency was entitled to take into

consideration.").[1] This litigation is currently on appeal and remained pending when HRSA suddenly and without explanation abandoned three decades of practice.

HRSA's Abrupt and Unexplained Announcement of a Rebate Program

52. At the same time the government attorneys representing Defendants were highlighting the risks of rebate programs in federal courts, and after thirty-three years of implementing the 340B Program through upfront discounts, HRSA abruptly announced that it was launching a 340B rebate program that would have a devastating financial impact on covered entities across the country, especially rural and other safety-net hospitals.

53. On July 31, 2025, HRSA announced a new "340B Rebate Model Pilot Program" via press release, followed by an initial notice in the Federal Register on August 1, 2025. *See* 90 Fed. Reg. at 36163. On August 7, 2025, HRSA reposted a largely identical announcement with corrections (the "Notice"). *See* 90 Fed. Reg. 38165.

54. The Notice, in summary, announced that HRSA would allow the manufactures of certain drugs to apply for the Rebate Program and submit their own proposed 340B rebate models to HRSA for review, with the intention for these models to go into effect on January 1, 2026. Under the Rebate Program, covered entities would be required to initially purchase these drugs at the WAC, and then wait for a rebate to be issued by drug companies.

55. Despite having argued only months before that the change from an "upfront discount" model to a "rebate" model would have a seismic effect on the 340B Program, the Notice

[1] The court overseeing the *Sanofi* litigation found that HRSA had acted arbitrarily and capriciously as to Sanofi. *Sanofi-Aventis U.S. LLC v. Kennedy*, No. 24-cv-03496, 2025 WL 1423630, at *13–14 (D.D.C. May 15, 2025). According to the court, HRSA had made a "determinative legal finding and final rejection" of Sanofi's proposed rebate model and therefore needed to consider all important aspects of the problem before making that determination. *Id.* at *13. HRSA conceded that "the administrative record [did] not address [numerous] concerns that Sanofi and the other plaintiffs raised[,]" which was "dispositive." *Id.* at *14.

contained little justification or explanation for the Rebate Program. The Notice principally stated that HRSA had "received inquiries" from drug companies about the upcoming implementation of the Centers for Medicare and Medicaid Services ("CMS") Medicare Drug Price Negotiation Selected List, which imposed new "Maximum Fair Prices" for certain drugs in the Medicare context and foreclosed duplicate discounts under the 340B Program.[2] *Id.* The Notice nowhere acknowledged that stakeholders had previously explained that there were alternative methods for achieving such deduplication or that the purported benefits of Inflation Reduction Act ("IRA")/340B deduplication did not come close to outweighing the tremendous costs of a rebate model. Indeed, the Notice did not elaborate on why such a convoluted Rebate Program involving the transfers of hundreds of millions of dollars was necessary if the goal is really a data-checking deduplication exercise. Put another way, there is nothing in the Notice that rationally connects the Rebate Program to Defendants' purported goals.

56. The Notice described the proposed rebate system as a "voluntary 340B Rebate Model Pilot Program." *Id.* But the Rebate Program is neither voluntary nor a "pilot" in any traditional sense of the word. Pilot programs are ordinarily limited in scope, whereas the "340B Rebate Model Pilot Program" is unquestionably not. While HRSA offered a few drug companies the option to participate in the pilot, *every single* 340B participating safety-net hospital and other

[2] The CMS Medicare Drug Price Negotiation Selected List is a new pricing regime for certain Medicare drugs established through the IRA. Pursuant to the IRA, CMS negotiated a "Maximum Fair Price" for drugs with the highest Medicare Parts B and D expenditures and no generic or biosimilar competitors and that have been marketable for at least seven years (for drugs) and 11 years (for biologics) (*i.e.*, products that have had little market competition). *See* 42 U.S.C. §§ 1320f *et seq*. CMS was required to negotiate the price of up to ten drugs for price applicability year 2026, up to fifteen for initial price applicability years 2027 and 2028, and up to twenty for initial price applicability year 2029 and subsequent years. *Id.* § 1320f-1(a)–(b). Drug manufacturers must offer 340B covered entities the lesser of the Maximum Fair Price or the 340B ceiling price, and these discounts may not be duplicated. 42 U.S.C. § 1320f-2(d).

covered entity in America is required to participate to obtain the 340B savings for the pilot drugs. HRSA did not seek a smaller pool of 340B providers to volunteer for a pilot program. It did not incentivize certain 340B hospitals to participate. Nor did HRSA consider using a regional model to experiment with the concept of rebates, excluding particular hospitals from the administrative burden of a pilot program, or any other of the many obvious narrower and less burdensome alternatives.

57. Likewise, the Notice did not address any of the concerns about the rebate model's financial impact on safety-net hospitals and other covered entities that HRSA itself had raised in the past, including in its 2024 letters to drug companies and the ensuing litigation. The Notice itself provided no estimate of the costs associated with complying with the pilot program; no explanation about why HRSA believed those costs (or any costs of compliance) to be reasonable; and no explanation about why imposing costs upon all covered entities was necessary in light of the purportedly limited purpose of the "pilot program."

58. Moreover, HRSA did not publish any clear or binding rules for drug manufacturers to follow in implementing their rebate programs. Instead, HRSA published vague, non-binding "criteria" for the rebate programs.[3] *Id.* at 38166–67. For example:

a. The Notice indicates that "all costs for data submission through an Information Technology (IT) platform be borne by the manufacturer and no additional administrative costs of running the rebate model shall be passed onto the covered entities." *Id.* at 38166 (Criterion #1). But the Notice provides no definition of "administrative costs" or explanation for how it expects covered entities are to

[3] Although HRSA included a series of "criteria" in the Notice, drug companies had the option of deviating from the criteria so long as they provided justification. *Id.* at 38166. HRSA has not indicated whether it approved any drug company applications that deviated from these criteria.

avoid such costs. Indeed, as discussed below, HRSA itself subsequently concluded that hundreds of millions of dollars in administrative costs would *not* be borne by drug companies and instead passed onto covered entities.

b. The Notice indicates that a "[p]lan should ensure that all rebates are paid to the covered entity (or denied, with documentation in support) within 10 calendar days of data submission." *Id.* (Criterion #12). But the Notice provides no criteria for a method of resolving disputes, the evidentiary burden or bases that drug companies are to use when evaluating claims, or any other key details. This is particularly troubling because HRSA had previously stated that the lack of a clear dispute mechanism was one of the major concerns it had with drug companies' rebate proposals, but HRSA repeated the same mistake in the Rebate Program.

c. The Notice notes at one point that the Rebate Program would "facilitate other aims such as the prevention of 340B Medicaid duplicate discounts and diversion." *Id.* at 38165. But later in the Notice, HRSA made clear that each company's "[p]lan should ensure that 340B rebates are not denied based on compliance concerns with diversion or Medicaid duplicate discounts." *Id.* at 38166 (Criterion #13). HRSA never reconciled this inconsistency. Critically, if drug companies cannot deny rebates based on program integrity concerns, the *only* conceivable purpose the Rebate Program can serve is the limited one of effectuating 340B/IRA deduplication.

59. HRSA wrongly claimed that the rebate model was informed by "the significant amount of feedback received from (or on behalf of) . . . covered entities regarding the

implementation of rebate models." *Id.* at 38165. Upon information and belief, this program was developed in meetings between drug companies and HRSA.

60. Subsequent to publishing the Notice, in August 2025 HRSA launched a website for the new Rebate Program that included a section entitled Frequently Asked Questions (FAQs). *See* HRSA, *340B Rebate Model Pilot Program*, (Nov. 2025), https://www.hrsa.gov/opa/340b-model-pilot-program (hereinafter the "FAQs"). The FAQs provided no meaningful details about the agency's reason for abandoning the upfront discount model it had championed for the previous three decades.

a. The FAQs did not address the massive costs that covered entities will bear under the Rebate Program, or why HRSA had suddenly decided that it was appropriate for covered entities to bear these costs, particularly after HRSA had previously objected to the imposition of such costs. *See id.*

b. The FAQs did not acknowledge or address any of the concerns HRSA itself had identified regarding rebate models, including those that HRSA raised in its 2024 letters to drug companies and the follow-on litigation. *See id.*

c. The FAQs were silent about why HRSA had not chosen narrower alternatives for the "pilot" program, such as voluntary participation for 340B providers, a regional pilot program, or a program that excludes financially fragile 340B providers. *See id.*

d. The FAQs underscored the lack of any enforceable deadline for drug companies to pay rebates. They suggested only that "[i]f a claim takes longer than 10 days for a rebate to be paid, covered entities and manufacturers should work to resolve the issue." *Id.* So, while HRSA had criticized the J&J proposal in September 2024

because it did "not commit to an enforceable timeframe for issuing the 'rebate payment,'" 340B_REBATES_000203, less than a year later, HRSA greenlit (with no explanation) a rebate pilot with no functionally enforceable timeline for paying rebates.

e. The FAQs did not identify a true process for adjudicating disputes between covered entities and drug companies if they could not "resolve the issue" themselves. The FAQs stated only that "[i]f after attempting to work with the manufacturer a covered entity cannot resolve the issue with the manufacturer, the covered entity should email 340BPricing@hrsa.gov with the details of its concern. A manufacturer that is consistently unable to timely resolve rebate reimbursement issues may have its participation in the pilot program revoked." The FAQs. The FAQs did not specify who would be reviewing complaints sent to this generic inbox; what it meant by "consistently unable"; what it meant by "timely"; how HRSA would gather facts or arguments about the dispute; or whether there was any way to ensure payment of the statutorily-owed discounts short of kicking a drug company out of the Rebate Program. *See id.*

f. The FAQs did not address concerns and complaints about the drug companies' chosen software platform, "Beacon." *See id.*

61. To implement the Rebate Program, HRSA directed manufacturers of the ten drugs in question to submit plans for their rebate programs by September 15, 2025. The drug companies were told to submit plans directly to HRSA without subjecting them to public scrutiny. Despite the massive implications for the U.S. healthcare system, HRSA did not request or require that the proposed plans contain any empirical data about the potential impact on the 340B Program's

implementation or the affected covered entities. Alarmingly, HRSA demanded that proposals "not exceed 1,000 words," 90 Fed. Reg. at 38166—a grossly inadequate number for a program that threatened the delivery of healthcare to millions of Americans.

62. Importantly, the drugs selected for HRSA's 340B "pilot" program are not the types of limited-purpose drugs that one would rationally select if the goal was to measure a new model without disrupting a massively critical program like the 340B Program. All ten drugs are high-volume, high-cost brand-name drugs with a substantial impact on the healthcare system, which is why they were also selected for initial Medicare price negotiation. If the supply of these drugs to rural hospitals and other 340B providers is disrupted under the Rebate Program—for example, if safety-net providers cannot pay the new massive upfront costs—then patients' health and lives will be at risk. For example, Imbruvica is an enzyme inhibitor used to treat chronic lymphocytic leukemia, Waldenström's macroglobulinemia, and chronic graft-versus-host disease. Clinical trials have shown that Imbruvica can improve the survival rate of leukemia patients by up to 56%, and Imbruvica is a last line of defense for patients rejecting their skin grafts after other therapies have failed. Losing access to Imbruvica jeopardizes patients' lives.

HRSA Concedes That the Rebate Program Will Cost Hospitals and Other Covered Entities Hundreds of Millions of Dollars

63. HRSA's Notice was entirely silent about the costs that would accompany the Rebate Program. Weeks after publishing the Notice, however, HRSA acknowledged elsewhere the exorbitant administrative costs its Rebate Program would impose on covered entities. But HRSA, again, never evaluated the necessity of these costs, whether these costs outweighed the benefits of a rebate program, or why its own implicit cost-benefit analysis had changed in the matter of months.

64. Under the Paperwork Reduction Act of 1995, 44 U.S.C. § 3501, *et seq.*, ("PRA"), HRSA was required to calculate the Rebate Program's burden on affected entities, including the time they would spend to generate, maintain, retain, disclose, or provide the data requested. HRSA did so in an Information Collection Request ("ICR") submitted to the Office of Information and Regulatory Affairs ("OIRA"). In August 2025, HRSA completed its ICR, in which it estimated that the proposed Rebate Program would require covered entities to expend over **1.5 million hours** in 2026 to comply with the data collection requirements. HRSA's monetary quantification of these hours was $200,428,800.

65. Viewed another way, HRSA calculated that the burden imposed on covered entities was *more than 4,000 times* the burden that would be imposed upon drug companies, which HRSA calculated would only amount to 360 hours per year to comply with the Rebate Program's data collection requirements.

66. HRSA submitted the following chart of administrative costs associated with the Rebate Program, with the rows "Lawyer" and "Accountant" reflecting the drug companies' costs, and the "Pharmacist" row reflecting the 340B providers' costs:

Type of Respondent	Total Estimated Burden Hours	Hourly Wage Rate	Total Respondent Costs
Lawyer	72	$176.00/ hour[4]	$12,672
Accountant	288	$90.00/ hour	$25,920
Pharmacist	1,518,400	$132.00/hour	$200,428,800
Estimated Total	**1,518,760**	-	**$200,467,392**

67. HRSA's calculations about the burden on 340B providers are staggering on their own. But those numbers grossly undercount the actual burden that the Rebate Program will place on covered entities. HRSA's estimate of 1.5 million hours is based on the notion that 14,600

covered entities will each spend *only 2 hours per week* complying with the requirements of the Rebate Program. But many providers will need to hire full-time staff just to comply with the administrative burden of the new 340B Rebate Program. Full-time means *full*-time—far more than two hours a week. In reality, the collection and submission of the requisite data will take many hospitals dozens of hours per week. *See infra*, ¶¶ 73–80. Tellingly, HRSA has provided no explanation for the basis of its two-hour calculation, and HRSA has offered no evidence that this estimate was empirically tested or validated.

68. The Rebate Program's actual administrative burden on 340B providers will be far higher than the 1.5 million hours and $200,428,800 that HRSA estimated.

69. While HRSA included these estimated administrative costs in its ICR submitted to OIRA, HRSA never updated its Notice or its FAQs to reflect this. Nor did HRSA provide any other public explanation about the value or necessity of imposing hundreds of millions of dollars in costs upon covered entities, whether there was an alternative means of avoiding or reducing those costs, or what benefits outweighed these extraordinary costs.

70. Likewise, while this calculation addresses the administrative costs of compliance, it does not calculate or address the upfront-payment costs that providers will be forced to bear in paying the far-higher WAC under the Rebate Program, rather than receiving the upfront discount. While HRSA had repeatedly expressed concern about those upfront-payment costs in prior positions and litigations, HRSA never discussed the size or impact of upfront-payment costs in connection with its Rebate Program.

71. Nor did HRSA identify or evaluate the *non-monetary* costs that its Rebate Program would impose on patients and communities as a result of the Rebate Program, including reduced access to comprehensive healthcare.

HRSA Receives Over 1,100 Comments About the Flaws in the 340B Rebate Program

72. In its Notice, HRSA solicited comments to be submitted within 31 days, although the agency took the position that it "will consider comments received but is under no obligation to respond to or act on the comments." 90 Fed. Reg. at 38165. Despite this short deadline for responses,[4] HRSA received more than 1,100 comments. Commenters flagged concerns about the scope of the Rebate Program, the administrative and operational challenges of the Program, and the costs that the Rebate Program would impose on covered entities, particularly rural and other safety-net hospitals. The comments also proposed multiple obvious and less-burdensome ways to address the IRA/340B deduplication concerns that HRSA described as the motivating purpose for its proposed Rebate Program. And many covered entity commenters raised concerns about their ability to meet a January 1, 2026 effective date.

The Rebate Program Will Impose Increased Administrative Costs

[4] Plaintiff AHA and other organizations representing hospitals asked HRSA to extend the comment period. Their letter stated:

> A change of this magnitude requires careful consideration by all stakeholders. To that end, the agency is seeking comments on its pilot program by September 8 and has asked drug manufacturers to submit rebate model plans by September 15. That timeline gives the agency only one week to consider any stakeholder feedback, make any necessary changes to its program, and communicate those changes to all 340B stakeholders, including the drug company applicants. With the fundamental changes a rebate model will impose on all 340B stakeholders, it is impossible for the agency to meaningfully consider, in just seven days, all the feedback it will surely receive. Moreover, drug companies have spent years developing and preparing for a rebate model, but the agency's current timeline would give 340B hospitals far less time to prepare.

Comment ID HRSA-2025-0001-0005 at 1 (all comments available at https://www.regulations.gov/docket/HRSA-2025-0001/comments). HRSA never responded to this request and forged ahead with its abbreviated comment timeline.

73. Commenters carefully described the increased administrative costs and burdens that the Rebate Program will impose on covered entities. Many noted that under the program, they would need to hire additional staff to (a) comply with the significant data collection and submission requirements, (b) track whether their hospital actually received a rebate, and (c) handle the inevitable disagreements with drug companies and navigate HRSA's opaque dispute resolution process.

74. Commenters also identified costs resulting from having to manage two discount systems. Covered entities will have to prepare, submit, and track one set of data for the traditional upfront discount program, and then prepare, submit, request and track rebates, and reconcile payments for HRSA's new Rebate Program. Covered entities operating on thin or negative margins commented that they do not have the budget and resources to do both.

75. Commenters also responded that while the Notice suggested that "administrative costs" would not be passed to covered entities, nowhere does the final program actually provide for these costs to be borne by drug companies.

76. As noted above, HRSA itself estimated that claims submission will cost covered entities at least $200 million annually, based on the assumption that providers will incur two hours of extra administrative burden per week. A number of commenters warned that HRSA's estimates for complying with the new 340B rebate program—two hours per week—were wildly unrealistic. For example, Plaintiff AHA reported that its "member hospitals . . . may need, on average, two additional full-time equivalents (FTEs) to gather the appropriate data, submit the data in the format required under the drug company's IT platform, and track the data to ensure the appropriate rebates are paid." Comment ID HRSA-2025-0001-0052 at 13. Likewise, multiple other covered entities noted that the administrative costs of complying with the new rebate model program would require

them to hire or reassign full-time employees—drawing resources away from the provision of healthcare in the name of complying with new bureaucracy. *E.g.*, Comment IDs HRSA-2025-0001-0099 at 1, HRSA-2025-0001-0110 at 3, 5.

77. A non-profit health center in Florida likewise wrote that "health centers will need to hire or reassign existing staff to untangle the mentioned complexities related to varying data submission requirements, timelines, and systems." Comment ID HRSA-2025-0001-0215 at 3.

78. This resource commitment means that HRSA's own estimates of cost and burden were highly inaccurate. Plaintiff AHA explained the true financial and operational impact of the Rebate Program in response to HRSA's notice of its intent to submit an Information Collection Request to the Office of Management and Budget per the Paperwork Reduction Act:

> With currently over 2,700 340B hospitals, that would amount to nearly 11.2 million burden hours — a far cry from the agency's estimates. Moreover, 340B hospitals indicated to us that the operational costs associated with the rebate model could range from $150,000 to over $500,000 per hospital, with costs increasing further if there are significant delays and denials with the rebate payments. Even a conservative estimate would yield over $400 million in annual costs for 340B hospitals to comply with the rebate model. And these costs don't include the millions of dollars 340B hospitals would be providing to drug companies as interest-free loans through the rebate model.[5]

Am. Hosp. Ass'n, *AHA Letter to HRSA re: The 340B Rebate Model Pilot Program* (Sept. 30, 2025), https://www.aha.org/lettercomment/2025-09-30-aha-letter-hrsa-re-340b-rebate-model-pilot-program.

79. Commenters further stressed that the process for addressing claim denials would impose unique administrative costs. They emphasized that there would be administrative costs

[5] Importantly, these estimates apply only to the burden and costs that would borne by the 2,700 340B hospitals. They do not cover the costs of the approximately 14,600 340B covered entities that are not hospitals.

because HRSA's guidance on how covered entities should handle the denial of claims for rebates is threadbare. Multiple commenters identified the "dangerously insufficient" gaps in HRSA's dispute resolution system and the unaccounted-for costs of those gaps. *E.g.*, Comment IDs HRSA-2025-0001-0052 at 5–6, HRSA-2025-0001-0076 at 5–6, HRSA-2025-0001-1074 at 5–6. In addition to highlighting the lack of information about how the dispute resolution would operate, covered entities warned that it will allow drug companies "to weaponize the alternative dispute resolution process by leveraging it to further delay rebates and/or discourage covered entities from pursuing the accrued rebates due to the complexities and burden associated with pursuing such a claim." Comment ID HRSA-2025-0001-0378 at 3.

80. Commenters such as Plaintiff AHA made the commonsense recommendations that drug manufacturers should be required to provide (a) a clear, detailed reason for claim denials, including "a narrative description of why a rebate claim is being denied"; (b) "supporting primary source materials . . . justifying such a denial"; and (c) "a signature or attestation by a drug company employee, along with their telephone number or email address, so that covered entities can reach them to address any incorrect denials." Comment ID HRSA-2025-0001-0052 at 6. This would serve as the foundation for covered entities and drug companies to meaningfully engage when attempting to resolve the issue, as required by HRSA's meager FAQs. HRSA did not address these suggestions.

The Rebate Program Will Impose Enormous Costs Due To Delayed Payment

81. Several commenters focused on the calamitous effects of cash-strapped covered entities having to float billions of dollars to drug companies each year while waiting for their statutorily-owed discounts. The enormity of these new upfront-payment costs was described by providers large and small.

82. One community health center in Fargo, North Dakota calculated the difference for a single pilot drug, Jardiance. Comment ID HRSA-2025-0001-0842 at 2. The 340B price for a 90-day supply of Jardiance is about $25 for this provider (28 cents per dose times 90), and its patients pay $7.00. *Id.* But, under the Rebate Program, covered entities will have to float approximately $1,800 per 90-day supply until the drug manufacturer rebates the difference. *Id.* Given the exorbitant upfront costs that must be paid under the Rebate Program, as well as the risks of delays in reimbursement, this commenter had already investigated obtaining loans from drug wholesalers to enable it to acquire those drugs. The costs of loans will be difficult for covered entities to bear, however. "At least one wholesaler charges 18% annual interest, and even the Small Business Administration charges 12.5% annually." *Id.* at 4.

83. A nonprofit membership organization with more than 1,600 public and private non-profit hospitals and health systems that participate in the 340B Program estimated that each of its hospitals would need to float, on average, $8.6 million annually to drug manufacturers. Comment ID HRSA-2025-0001-1111 at 4. This multi-million-dollar annual outlay, the organization warned, would generate major liquidity challenges for safety-net providers. As a result, those healthcare providers would ultimately reduce access to care and services for low-income patients.

84. Similarly, one healthcare consulting company measured the potential financial impact of the Rebate Program by the costs that 81 covered entities would have incurred had the rebate program been operative in 2025. Comment ID HRSA-2025-0001-0076 at 1–2. This commenter calculated that the 81 covered entities would have needed to float drug companies more than $348 million under the rebate model just for these 10 drugs for only the first six months of 2025. *Id.* As the commenter concluded, "[t]he most significant hidden cost of the rebate model

for covered entities is the time value of money—the financial impact of advancing millions in drug spend while waiting for reimbursement." *Id.* at 3.

85. Several commenters noted that the need to stock drugs at facilities would mean weeks or months would elapse before covered entities were reimbursed for the millions of dollars paid initially to the drug companies. Put another way, the program's 10-day rebate requirement program would have diminished value because some drugs sit on the shelf for longer periods of time before being dispensed. For example, two regional providers noted "several months may pass between the time of purchase and the time of dispensing [a drug]. Under the rebate model, covered entities would be required to absorb the higher upfront cost for an indefinite period[,]" compounding the difficulties covered entities will face covering the enormous upfront costs. Comment ID HRSA-2025-0001-0378 at 3; *see also* Comment ID HRSA-2025-0001-0401.

86. Commenters, including Plaintiff AHA, noted that these upfront-payment costs and attendant loss of liquidity would have real-world implications for the provision of healthcare. Plaintiff AHA explained that these costs would undermine the ability of covered entities to expand coverage to underserved geographies, refresh medical equipment, and invest in other capital-intensive projects that benefit the communities these hospitals serve. Comment ID HRSA-2025-0001-0052 at 12–14. Plaintiff AHA also warned that requiring such a substantial outlay could have devastating collateral consequences on hospitals' finances, such as violating bond covenants that require hospitals to maintain a certain amount of cash on hand, which could lead to a spiral of downgrades in credit ratings, increased borrowing costs, and even closure. *Id.*

Obvious and Less Burdensome Alternatives to a Rebate Program

87. Commenters submitted several alternatives to the Rebate Program that would address the underlying concerns flagged by HRSA in its Notice. They noted that HRSA's only

stated justification for the Rebate Program was to address the risk of duplicated discounts—that is discounts under both the 340B Program and Medicare's maximum fair price under the IRA. But, these commenters explained, IRA/340B duplication could have been addressed by less costly and less disruptive mechanisms.

88. Many of these proposed alternatives involved a neutral, third-party entity that would facilitate the collection and adjudication of claims data to facilitate deduplication. For instance, one commenter suggested that HHS rely on a government-backed "clearinghouse" to exchange information between covered entities and drug companies. Comment ID HRSA-2025-0001-0974 at 6–7. HHS has already established a clearinghouse in two contexts related to IRA implementation—one of which was *specifically designed* to collect 340B claims data.

a. The first, called the Medicare Transaction Facilitator, was established to facilitate access to Medicare's maximum fair price by serving as a data and payment exchange between dispensing entities and manufacturers.[6] Plaintiff AHA explained in a comment letter that a rebate program was unnecessary to avoid duplication because HRSA could rely on the preexisting Medicare Transaction Facilitator as an alternative. AHA noted, "drug companies [could] make access to the [maximum fair price] for Medicare negotiated drugs available *prospectively* as is currently done for drugs purchased under the 340B Program." Comment ID HRSA-2025-0001-0052 at 11. This alternative:

> would allow dispensing entities, like hospitals and pharmacies, to purchase Medicare negotiated drugs at either the drug's maximum fair price or 340B price, whichever price is lower for that particular drug. Dispensing entities would then submit certain data to CMS'

[6] *See* Centers for Medicare & Medicaid Services, *Medicare Transaction Facilitator (MTF) Overview for Dispensing Entities* (Apr. 2025), available at https://www.cms.gov/files/document/pharmacy-and-dispensing-entity-mtf-fact-sheet.pdf.

> Medicare Transaction Facilitator (MTF), which would verify that the dispensing entity purchased the drug at the correct price. If the purchase was made at the incorrect price, the MTF could facilitate a transfer of funds between the drug company and the dispensing entity to rectify the error.

Id. This proposal makes intuitive sense, because HHS itself has acknowledged that drug companies are not required to make access to Medicare's maximum fair prices retrospectively and may choose to make access to maximum fair prices *prospectively*, which is exactly what AHA recommended in place of the Rebate Program.

b. The second existing clearinghouse, called the Part D claims repository, was established to collect 340B claims data to identify and exclude Part D drug units purchased under 340B for the purpose of calculating Medicare inflation rebates as required under the IRA. Commenters, including Plaintiff AHA, identified this new "clearinghouse" as a viable alternative to address IRA/340B deduplication, since CMS proposed to use this data repository to identify 340B units for the calculation of Medicare inflation rebates required under the IRA.[7] *Id.* at 5. Defendant HRSA was completely silent on the Part D claims repository "clearinghouse" alternative in connection with its approval of the Rebate Program.

Obvious and Less Burdensome Versions of a Rebate "Pilot"

[7] Notably, HHS released its final 2026 Physician Fee Schedule rule on October 31, 2025—only one day after it approved drug companies' applications to participate in the Rebate Program. That final rule adopted the Part D claims repository "clearinghouse" alternative in that context. But despite receiving multiple comments suggesting that this same "clearinghouse" could be used in place of the costly and complex Rebate Program, Defendants never explained why they chose a clearinghouse in one IRA/340B deduplication context but not the other.

89. Commenters also highlighted less costly alternatives to the structure of HRSA's mandatory-for-covered-entities Rebate Program. For example, if this were truly a pilot to test the efficacy and practicalities of a rebate program, commenters noted that HRSA should have begun with a more limited scope of covered entities and drugs, consistent with the past practice of federal healthcare agencies.

90. One commenter stated: "HHS has a long history of testing new policies through limited demonstration programs, such as state-driven Section 1115 waivers for the Medicaid program and experimental Medicare models from the Centers for Medicare and Medicaid Innovation. The Notice fails to consider whether the 340B Rebate Program's goals could be achieved through a more limited model, such as one open to covered entity volunteers." Comment ID HRSA-2025-0001-0974 at 8.

91. Commenters separately noted that the proposed pilot was "overbroad with regard to in-scope drugs. The 340B Rebate Pilot is open only to manufacturers of drugs that are on the CMS Medicare Drug Price Negotiation Selected Drug List ('MDPNP List'). By design, the drugs on the MDPNP List are among the most-prescribed drugs for Medicare beneficiaries. From June 2022 through May 2023, these drugs made up about 20% of total Part D gross covered prescription drug costs. The Notice fails to consider whether a pilot open to fewer drugs could achieve the Deduplication goals stated in the Notice." *Id.*; *see also* Comment ID HRSA-2025-0001-1074 at 3–4.

Problems with the "Beacon" Software Platform

92. Commenters raised concerns about HRSA allowing the drug companies to select their own preferred technological platform to run the rebate program. The drug companies chose to hire a platform named Beacon Channel Management ("Beacon") as the exclusive conduit

through which covered entities must submit rebate claims. Beacon is run by Second Sight Solutions, LLC, which is itself owned by Berkeley Research Group ("BRG").[8]

93. One commenter explained: "When manufacturers proposed to use BRG's Beacon platform to impose a rebate model in 2024, covered entities were shocked at the non-negotiable terms and conditions ('Terms') required to access the platform. These Terms are designed to benefit BRG/Second Sight and its manufacturer clients and shift effectively all risk associated with data sharing to covered entities." Comment ID HRSA-2025-0001-0974 at 11.

94. Given these objectionable Terms, this commenter stated: "[A]t a minimum[,] self-serving and prejudicial terms such as those contemplated for rebate models such as the BRG/Second Sight Beacon platform noted above should be prohibited. Instead, standard terms and conditions developed and approved by HHS should be implemented to avoid the inappropriate utilization/monetization of data and application of unrelated terms benefiting manufacturers and their third party for-profit partners." *Id.* at 12.

95. This commenter identified a second important aspect of the problem: giving such broad authority to the creator of the Beacon software platform. It explained that "this approach serves to delegate HHS' 340B Program enforcement authority to a for-profit company as well as drug manufacturers with clear conflicts of interest." *Id.*

[8] In addition to owning Second Sight, BRG regularly publishes adversarial reports on the 340B Program, often with funding from drug companies. *See, e.g.*, Eleanor Blalock & Carlee Launsbach, *The Financial Impact to Medicaid from the 340B Drug Pricing Program,* BRG (July 2025), https://www.thinkbrg.com/insights/publications/the-financial-impact-to-medicaid-from-the-340b-drug-pricing-program/ (describing study funded by Pharmaceutical Research and Manufacturers of America).

96. Another commenter specifically attached Beacon's Terms to its comment letter, explaining that Beacon's contract included terms that the covered entity "would not be able to agree to." Comment ID HRSA-2025-0001-0951 at 5. Complaining that Beacon's terms and conditions would be forced on it, this commenter asked HRSA to "[a]llow for covered entity negotiation power on Terms and Conditions." *Id.*

97. Commenters additionally raised "significant data privacy and cybersecurity concerns associated with" Beacon and urged that "[a]ny platform utilized must provide verifiable assurances regarding the confidentiality, integrity, and availability of protected health information (PHI) and personally identifiable information (PII)." Comment ID HRSA-2025-0001-0495 at 1; *see also* Comment ID HRSA-2025-0001-0106 at 2.

Problems With the January 1, 2026 Effective Date

98. Numerous commenters identified problems with the proposed January 1, 2026 start date and asked HRSA to delay implementation. For example, Plaintiff AHA wrote: "A delay will allow HRSA to address the many operational and administrative problems that the AHA and others identified" in the many comment letters the agency received on its pilot program notice. The Am. Hosp. Ass'n, *AHA Letter to HRSA re: The 340B Rebate Model Pilot Program* (Sept. 30, 2025), https://www.aha.org/lettercomment/2025-09-30-aha-letter-hrsa-re-340b-rebate-model-pilot-program.

99. Another commenter explained: "It is difficult to comprehend how HRSA will be able to review comments on this demonstration, make corrections to potential design flaws, and ensure that this demonstration is conducted fairly for covered entities, drug makers, and even HRSA within this compressed timeframe. We would suggest that HRSA at least delay the start of

the demonstration to address these concerns." Comment ID HRSA-2025-0001-0549 at 2 (emphasis omitted).

100. Other commenters noted the January 1, 2026, deadline placed unnecessary costs and burdens on 340B providers, and some simply would not be ready. One explained, "Implementing rebate programs beginning January 1st will put an immense burden on rural covered entities." Comment ID HRSA-2025-0001-0748 at 3. Another stated: "Giving notice of less than three months before implementation of such significant operational changes is not sufficient for covered entities to implement the infrastructure and staff needed to support the data submissions required to run these models and report the requested data.… [S]hould the Agency continue to pursue this pilot program the Agency must push back the application deadline and effective date to give covered entities and manufacturers ample time to implement." Comment ID HRSA-2025-0001-0465 at 5.

HRSA Ignores the Comments and Launches a Broad 340B Rebate Program with No Explanation

101. Despite soliciting and receiving over 1,100 comments during a month-long period, HRSA *has not responded to a single one*. Instead, HRSA's Notice stated that it "will consider comments received but is under no obligation to respond to or act on the comments." 90 Fed. Reg. at 38165. That is emphatically an incorrect statement of law. *See W. Coal Traffic League v. Surface Transp. Bd.*, 998 F.3d 945, 954 (D.C. Cir. 2021) ("[T]he failure to respond to significant comments . . . violates a substantive guarantee of the APA."). Among other things, HRSA must consider important aspects of the problem, supply a satisfactory explanation for its actions, demonstrate consideration of reliance interests when changing policy, and offer explanations consistent with the evidence before it. *See e.g.*, *Ohio*, 603 U.S. at 293–94; *State Farm,* 463 U.S. at 52.

102. HRSA's refusal to respond to comments also is in stark contrast with HRSA's past practice. HRSA has a long history of soliciting *and responding* to feedback, considering viable alternatives, and providing a reasoned explanation for its actions. For example, in December 1993, HRSA requested and, in May 1994, responded to comments on its proposal for covered entity use of discounted drugs. In August 1997, HRSA requested public comments on the potential of switching from a discount model to rebate model for State AIDS Drug Assistance Programs ("ADAPs"). And in June 1998, HRSA responded to "all major comments"—and made "several modifications based upon the comments"—in publishing the guidelines for the ADAP rebate program. HRSA has engaged in numerous other policymaking exercises where it solicited, substantively responded to, and incorporated comments.[9]

103. As of the date of filing this Complaint, HRSA has yet to address concerns regarding, among others: (a) the underlying rationale for the program, and an explanation of its about-face on the costs and other downsides of a 340B rebate model; (b) the obvious value of running a more limited pilot program rather than imposing it on all of the 14,600 340B covered entities; (c) the staggering costs of the proposed rebate program, particularly as compared to its

[9] *See, e.g.*, Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Contracted Pharmacy Services, 60 Fed. Reg. 55586 (Nov. 1, 1995) and Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549 (Aug. 23, 1996) (requesting comments and noting that "all comments were considered" in propagating final guidelines on guidelines for contract pharmacies); Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 60 Fed. Reg. 39762 (Aug. 3, 1995) and Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996) (same for guidelines regarding definition of covered entity "patient"); Notice Regarding the 340B Drug Pricing Program; Children's Hospitals, 72 Fed. Reg. 37250 (July 9, 2007) and Notice Regarding 340B Drug Pricing Program—Children's Hospitals, 74 Fed. Reg. 45206 (Sept. 1, 2009) (same for adding children's hospitals to 340B Program); Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 72 Fed. Reg. 1540 (Jan. 12, 2007) and Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (Mar. 5, 2010) (same for contract pharmacies).

narrow purpose and limited benefits; (d) the absence of any meaningful dispute resolution process; (e) the obvious, less-intrusive alternatives to address deduplication; (f) concerns about the Beacon platform; and (g) the challenges of implementing this Rebate Program in just a few months and the manifest need for delayed implementation.

104. Instead of responding to public comments, HRSA has barreled on with the program, reviewing and approving the rebate plan applications that were privately submitted by eligible drug companies without any input from the 14,600 covered entities. These applications were due on September 15, 2025.

105. On October 30, 2025, HRSA announced via its website that it had approved nine drug companies' applications for a total of nine drugs with a January 1, 2026, effective date. HRSA did not provide any further explanation of what criteria the agency used or what, if any, modifications it required from the drug companies.

106. On November 14, 2025, HRSA announced that it had approved a plan from Novartis Pharmaceuticals Corporation to include a tenth drug, Entresto, in the Rebate Program, with the effective date of April 1, 2026. [10]

107. To date, HRSA has not made any of the applications available for public review.

108. Importantly, the drugs selected for HRSA's 340B "pilot" program are not the types of limited-purpose drugs that one would rationally select if the goal was to measure a new model without disrupting a massively critical program like the 340B Program. All ten drugs are high-

[10] The approved applications are for the following drugs and drug manufacturers: Eliquis (Bristol Myers Squibb); Enbrel (Immunex Corporation); Farxiga (Astra Zeneca AB); Imbruvica (Pharmacyclics); Januvia (Merck Sharp Dohme); Jardiance (Boehringer Ingelheim); Novolog, Novolog Flexpen, Novolog Penfill, Fiasp, Fiasp Flextouch, and Fiasp Penfill (Novo Nordisk Inc.); Stelara (Janssen Biotech, Inc.); Xarelto (Janssen Pharmaceuticals, Inc.); and Entresto (Novartis Pharmaceuticals Corporation).

volume, high-cost brand-name drugs with a substantial impact on the healthcare system, which is why they were also selected for initial Medicare price negotiation. If the supply of these drugs to rural hospitals and other 340B providers is disrupted under the rebate model—for example, if safety-net providers cannot pay the new massive upfront costs—then patients' health and lives will be at risk.

109. Since receiving over 1,100 comments, HRSA has not filed any new notice or equivalent statement in the Federal Register, has not addressed the comments as required under the APA, and has not given further explanation or published any other indication that it considered the comments it received or evaluated the proposed program in light of public feedback.

110. In particular, HRSA has never analyzed the vast costs of its pilot program, the necessity of those costs, and how those costs compare to any benefits that could flow from the program. Put differently, HRSA has never addressed *the very same cost concerns* that it previously flagged for Eli Lilly, J&J, and other drug companies in 2024 that a rebate model inherently generates "significantly higher up-front costs for covered entities" or that "widespread adoption of rebate models would cause unprecedented disruption to the [340B] program." 340B_REBATES_000292, 340B_REBATES_000064 (both filed in the *Eli Lilly* Case, Dkt. 60-1).

111. Tellingly, HRSA's disregard for costs was so obvious that it announced its final decision about the drugs for the Rebate Program *weeks before* the comment period under the Paperwork Reduction Act had even closed. That period, provided for under federal law, allows the public to comment on the necessity of the proposed information collection, the accuracy of the estimated burden (time and cost), ways to enhance the quality and utility of the information, and ways to minimize the burden on respondents. HRSA did not even wait to see whether its estimate of cost and burden was accurate.

112. Furthermore, HRSA showed a blatant disregard for the public's comments by submitting a "Request for Emergency Approval" to Jeffrey Clark, the Acting Administrator of the Office of Information and Regulatory Affairs ("OIRA") on August 25, 2025. This request was submitted pursuant to the Paperwork Reduction Act, which requires OIRA to approve of any agency solicitation of information from the public.

113. This August 25, 2025 submission to Mr. Clark was legally concerning for two reasons. *First*, the Paperwork Reduction Act request for public input on cost and burden was *not* included with the original Rebate Program announcement. Usually, such requests are included when new rules or programs are proposed or announced. The nearly one-month delay of this request is strong evidence that Defendants did not care at all about the costs their new program would impose. At the very least, it is further evidence of the Defendants' slipshod approach to this Rebate Program.

114. *Second*, Defendant Engels described the need for a shortened Paperwork Reduction Act timeline as an "emergency." In so doing, he demonstrated that he and other Defendants were unalterably committed to acceding to drug company requests to implement rebate models under 340B as a way to deduplicate 340B discounts and the IRA's Medicare Fair Price by January 1, 2026. Defendants' characterization of that January 1 date as an "emergency" indicates that Defendants did not have an open mind about whether to move forward with this so-called "pilot" program, but rather intended to press forward as quickly as possible.

115. Further demonstrating a disregard for the cost side of the equation, the "Request for Emergency Approval" was exclusively focused on what *drug companies* wanted or might do in the absence of a rebate model. For example, Engels stated: "[i]f HRSA does not receive emergency approval, then manufacturers may argue that they do not have the tools they need to effectuate

nonduplication of the MFP and the 340B discount." By contrast, nowhere in Engels' "Request for Emergency Approval" did he indicate any serious concern for the views of other regulated parties like 340B hospitals and other covered entities. Nor did he express any concern about the costs to patients, communities, and comprehensive healthcare in general.

A Lack of Deliberation and Guidance from HRSA Has Resulted in Chaos and Confusion in Advance of the Upcoming January 1 Implementation

116. Unsurprisingly, HRSA's handover of the Rebate Program to drug companies has caused chaos and uncertainty, which will, in turn, impose additional costs and administrative burden on covered entities. These costs and burdens are exacerbated by the exceedingly short time period before the program goes into effect on January 1, 2026.

117. To take one example, on November 20, 2025, Walgreens, the nation's second largest pharmacy chain, announced that it will temporarily stop processing 340B contract pharmacy claims for drugs included in the rebate program. According to public reporting, Walgreens told 340B providers with which it has contracted to distribute drugs that it is diligently working to prepare its systems to support and participate in the rebate program, but the exact timeline for implementing system enhancements is still being determined. Not only will this further prevent 340B hospitals from obtaining vital statutory discounts, but it will hamper patients' ability to obtain drugs closer to where they live—a particular concern for hospitals serving rural populations. Walgreens' decision was a direct result of Defendants' rushed timeline for implementation; even a company of Walgreens' size and resources did not have enough time to update their systems to comply with the rebate model. 340B hospitals fear that other pharmacies will follow Walgreens' example and refuse to process claims for drugs included in the Rebate Program.

118. To take another example, several problems have arisen, as predicted in multiple comment letters, with the drug companies' chosen "Beacon" platform. Following HRSA's approvals, covered entities are now mandated to use the Beacon platform and must agree to Beacon's nonnegotiable terms of use to participate in the 340B program.

119. As predicted by multiple commenters, Beacon's terms are overwhelmingly one-sided and leave covered entities with little legal recourse should the platform fail to function adequately. For example, Beacon's take-it-or-leave-it contract includes a term that limits its aggregate liability for direct damages under the Rebate Program platforms agreements to $1,000. *Beacon Rebate Model Terms of Use*, Beacon (Oct. 1, 2025), available at https://cm.beaconchannelmanagement.com/pages/terms.

120. Given that Beacon will be handling millions of patients' data, as well as the transactions of billions of dollars' worth of claims, this limitation is preposterously low and essentially immunizes Beacon from its own negligence or harm it causes. HRSA has not insisted on any terms that would appropriately hold Beacon responsible in cases of malfeasance.

121. Even more concerning, HRSA is allowing Beacon to harvest and sell the patient data that covered entities must provide as part of this rebate program. This not only allows Beacon to profit enormously from 340B hospitals' data, but it also raises serious questions about compliance with federal and state privacy laws, with downstream consequences for patients and providers.

a. Section 3(a) of Beacon's "Rebate Model Terms of Use" states that covered entities grant a "worldwide, sublicensable, non-exclusive, royalty-free, perpetual, and irrevocable license to collect, process, disclose, create derivative works of, and otherwise use the Rebate Data ('Data License')[.]"

b. Section 3(a) also provides that the "Data License will survive termination of these Terms with respect to any Rebate Data submitted prior to termination." Even if HRSA elects to abandon the "pilot" program after a year, therefore, Beacon is permitted to retain the data for decades for its own commercial purposes. It can sell that data to drug companies, insurance companies, artificial intelligence companies, or anyone else who will recognize the significant value of hospitals' information. HRSA has offered no explanation for why it will allow Beacon to retain *and profit from* this data in the event that the program ends.

122. Upon information and belief, as of the time of the filing of this Complaint, HRSA has not even tested the Beacon platform that is so integral to the Rebate Program.

123. Since the approval of Beacon as HRSA's exclusive platform for the Rebate Program, numerous entities—including 340B vendors and third-party administrators—have warned HRSA of significant technical issues with the Beacon platform due to a lack of testing and completed integration. But HRSA has largely ceded control of the technical implementation of the Rebate Program to the drug companies and their chosen contractor. On information and belief, HRSA has taken no action to address these problems.

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

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

125. Beginning on January 1, 2026, as HRSA itself concedes, covered entities collectively will be required to spend hundreds of millions of dollars in administrative costs. Those costs are unrecoverable. Even today, weeks before the Program is set to go into effect, covered entities are expending substantial resources to comply with an agency action that is unlawful, but

they cannot seek damages from the federal government to recoup these costs. What's more, these costs were known to and ignored by HRSA as it rushed ahead with this Rebate Program to satisfy drug company "inquiries."

126. For instance, as both commenters and Plaintiffs have stated, they will be required to hire or divert staff to deal with the administrative side of the Rebate Program. Even small safety-net hospitals will have to deploy scarce headcount to comply with the new administrative burdens. Plaintiff St. Mary's anticipates needing to hire a full-time employee to handle the administrative burden of the Rebate Program. Plaintiff Nathan Littauer will be hiring one full-time employee due exclusively to the pilot program, and Plaintiff Dallas County Medical Center is hiring two, one in its pharmacy department and another in its accounting department. Covered entities operating on tiny margins (if any margin at all) simply do not have the requisite resources.

127. Any dollar spent on complying with the Rebate Program is one less dollar that hospitals can spend on patient care. As a result of the costs associated with the Rebate Program, covered entities will be required to close service lines, hire fewer clinicians, and delay replacing outdated and unrepairable medical equipment. All of those consequences will harm patients.

128. The safety-net provider Plaintiffs here are each at risk of curtailing services because of the increased costs of Defendants' Rebate Program, such as:

a. Plaintiff St. Mary's' use of its 340B savings to help reduce the price of some outpatient drugs for its patients and to offer an infusion therapy program in which eligible patients receive the drug for free.

b. Other hospitals in Maine that are members of MHA similarly use of their 340B savings to provide financial assistance to patients who cannot afford care; community-based health clinics at schools, nursing homes, and other easy-to-

access locations; and life-saving opioid intervention services (such as the provision of naloxone, suboxone, and methadone), which they will not be able to continue at their current levels if the Rebate Program becomes effective.

c. Plaintiff DCMC's recently opened cancer telehealth clinic, which spares patients the two-hour round-trip to see the nearest oncologist but is unprofitable.

d. Plaintiff Unity Medical Center's recently opened cardiac and pulmonary rehabilitation services.

e. Plaintiff Nathan Littauer Hospital's planned expansion of a new primary care clinic (for which it has already been gifted property).

129. With respect to delaying necessary improvements, for example, Plaintiffs have been unable to move forward with updates to their facilities with the Rebate Program looming. Plaintiff DCMC has been forced to delay critical maintenance on its boiler room and construction of a ramp for disabled patients at its occupational therapy clinic, among other facility improvements. Plaintiff Nathan Littauer Hospital has similarly put its pharmacy build-out on hold. These delays in Plaintiffs' ability to deploy capital for necessary projects causes irreparable harm to them and their missions.

Count I – 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; Decision Runs Counter to Evidence Before the Agency; Failure to Provide Reasonable Explanation)

130. Plaintiffs repeat, re-allege, and incorporate the allegations in the preceding paragraphs.

131. Defendants' establishment and upcoming January 1, 2026 implementation of the 340B Rebate Model Pilot Program, as well as their approval of drug company applications to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

132. The APA requires courts to "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), or is "in excess of statutory jurisdiction, authority, or limitations," *id.* § 706(2)(C), or is "unsupported by substantial evidence," *id.* § 706(2)(E); *see also Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 413–15 (1971); *U.S. Sugar Corp. v. EPA*, 113 F.4th 984, 997 (D.C. Cir. 2024).

133. Agency action is arbitrary and capricious if based on an unlawful interpretation of statute or regulations, or if it is "not rational and based on consideration of the relevant factors." *FCC v. Nat'l Citizens Comm. for Broad.*, 436 U.S. 775, 803 (1978). Furthermore, "agency action [must] be reasonable and reasonably explained," *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021), resulting in a "product of reasoned decisionmaking." *State Farm,* 436 U.S. at 52. Arbitrariness and capriciousness also results "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.* at 43. "These are merely 'examples'" of arbitrary and capricious agency action. *Penobscot Air Services, Ltd. v. FAA*, 164 F.3d 713, 720 (1st Cir. 1999) (quoting *Puerto Rico Sun Oil Co. v. United States EPA*, 8 F.3d 73, 77 (1st Cir. 1993)). "'[O]thers could be recited as well.'" *Id.* (quoting *Dubois v. United States Dep't of Agric.*, 102 F.3d 1273, 1285 (1st Cir. 1996)).

134. These black letter requirements are all the more important when there is a change—or reversal—in an established agency practice because the change can have dramatic effects on relevant parties' reliance interests. When an agency is "not writing on a blank slate," it is "required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *DHS v. Regents of the Univ. of Cal.*, 591 U.S. 1, 33 (2020)*; see also Perez v. Mortg. Bankers Ass'n,* 575 U.S. 92, 106 (2015) ("[T]he APA requires an agency to provide more substantial justification when 'its new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account. It would be arbitrary and capricious to ignore such matters.'" (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)).[11]

135. Defendants have not considered or addressed the interests of the more than 14,000 safety-net hospitals and other covered entities across the country that have relied on upfront discounts for more than 30 years. As HRSA has previously acknowledged, and as was repeatedly noted in the comments HRSA received, covered entities structure key operations and financial decisions on their ability to access drugs at discounted prices through the 340B program *without* a rebate model. They have built their IT systems and designed their contracts with third-party vendors based on an upfront discount model. They have made internal hiring decisions based on this long-standing model. And the thirty-plus year use of an upfront discount model informs covered entities' budgets, allows them to honor their debt covenants with lenders, helps them

[11] Indeed, counsel for the Defendants noted during a November 17, 2025 D.C. Circuit oral argument over drug companies' unilateral efforts to impose 340B rebate models that "*Fox v. FCC* says if you change your position there's a heightened standard for explaining it."

finance the expansion of care through capital-intensive projects, and ensures liquidity with these systems.

136. HRSA knows this. In court filings just months before the announcement of the rebate program, HRSA took the position that it "has long envisioned upfront discounts as the preferred price reduction mechanism" because covered 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 22, *J&J*, No. 24-cv-03188. HRSA has given no reasons for its fundamental change in position, nor has it addressed any of these important reliance interests in creating its new rebate model program.

137. Defendants disrupted thirty-three years of established practice on an unnecessarily hurried timeline, and without considering or responding to important aspects of the problems identified in the more than 1,100 HRSA-solicited comments. As the D.C. Circuit has emphasized, "the failure to respond to significant comments . . . violates a substantive guarantee of the APA.'" *Western Coal Traffic League v. Surface Transp. Bd.*, 998 F.3d 945, 954 (D.C. Cir. 2021); *Marasco & Nesselbush, LLP v. Collins*, 6 F.4th 150, 169 (1st Cir. 2021) ("Importantly, even if the rule is not subject to the notice-and-comment process, it is subject to review under the arbitrary and capricious standard."). Here, the commenters identified a host of serious problems with the rebate model. HRSA failed to consider or provide a reasoned explanation with respect to all of these problems.

138. Defendants also failed to consider comments raising problems with rushing the program into effect on January 1, 2026, despite the clear evidence that the participants will not be prepared to participate by that deadline. Many basic operational questions remain unanswered, even as of the filing of this complaint. On information and belief, for example, Defendants have

not bothered with the most basic implementation steps, such as testing the software platform on which the entire Rebate Program will rely. But, again, Defendants have not acknowledged, much less addressed, the host of operational challenges that have been raised, some of which were the basis for a request for delay. Indeed, as of the filing of this Complaint, HRSA has not provided a single response to—or even an acknowledgment of—any of the more than 1,100 comments (or problems identified therein). These omissions are fatal to the Rebate Program.

139. The APA's substantive requirements to respond to significant comments and not ignore important aspects of the problem exist for an important reason: to ensure that agencies reach the best outcomes. "[P]ublic participation assures that the agency will have before it the facts and information relevant to a particular administrative problem ... [and] increase[s] the likelihood of administrative responsiveness to the needs and concerns of those affected." *Am. Hosp. Ass'n v. Bowen,* 834 F.2d 1037, 1061 (D.C.Cir.1987) (omission in original) (alterations in original) (quoting *Guardian Fed. Sav. & Loan v. Fed. Sav. & Loan Ins. Corp.,* 589 F.2d 658, 662 (D.C.Cir.1978); *cf. Azar v. Allina Health Servs*., 587 U.S. 566, 582 (2019) (requiring agency to consider public comments "affords the agency a chance to avoid errors and make a more informed decision"); *see generally* Eugene Scalia, *The Value of Public Participation in Rulemaking*, The Regulatory Review (Sept. 25, 2017), available at https://www.theregreview.org/2017/09/25/scalia-public-participation-rulemaking/ ("We value public participation in rulemakings in part because it is an opportunity to bring valuable evidence to the agency's attention, to explain effects of a proposed rule that the agency may not have appreciated, and simply to bring a perspective that the agency itself otherwise would not have."). Defendants' abject disregard of public input here underscores Congress' wisdom in enacting these substantive APA requirements.

140. In a litigation filing earlier this year, Defendants appeared to acknowledge this. They emphasized that 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 manufactures to redesign the operation of the program." Dkt. 41-1 at 24, *J&J*, No. 24-cv-03188. And yet, months later, HRSA instituted the same changes in the 340B program that it had vociferously opposed, without any explanation. Defendants have, in their own words, neglected their duty.

141. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, all in violation of the Administrative Procedure Act.

Count II – Administrative Procedure Act

(Rebate Program Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law – Failed to Consider Costs and Benefits, an Important Aspect of the Problem; Decision Runs Counter to Evidence of Costs and Benefits Before the Agency)

142. Plaintiffs repeat, re-allege, and incorporate the allegations in the preceding paragraphs.

143. Defendants' establishment and upcoming January 1, 2026 implementation of the 340B Rebate Model Pilot Program, as well as their approval of drug company applications to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

144. "Agencies have long treated cost as a centrally relevant factor when deciding whether to regulate. Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages and the disadvantages of agency decisions." *Michigan v. EPA*, 576 U.S. 743, 752–53 (2015); *id.* at 769 ("Cost is almost always a relevant—and usually, a highly important—factor in regulation. . . . [A]n agency must take costs into account

in some manner before imposing significant regulatory burdens.") (Kagan, J., dissenting). Thus, 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 v. U.S. Dep't of Com.*, 60 F.4th 956, 973 (5th Cir. 2023) (quoting *State Farm*, 463 U.S. at 43). As part of that cost-benefit analysis, the agency must identify benefits that "bear a rational relationship to the . . . costs imposed." *Id.* Here, Defendants acted arbitrarily with respect to at least three types of costs: (a) administrative costs; (b) "upfront-payment costs," *i.e.*, costs associated with making full-price payments to drug companies while awaiting a rebate; and (c) non-monetary costs to patients and communities that will result from reduced access to healthcare.[12]

145. *First*, Defendants ignored the massive administrative costs involved with this program. Although Defendants referenced a $200 million estimate of administrative costs, they did not explain how they arrived at that figure. Defendants did not offer any data, surveys, or other empirical evidence to support that number. Indeed, Defendants' only written estimate of costs

[12] *See, e.g.*, *Business Roundtable v. SEC*, 647 F.3d 1144, 1148–49 (D.C. Cir. 2011) ("Here the Commission . . . failed adequately to quantify the certain costs or to explain why those costs could not be quantified; neglected to support its predictive judgments; contradicted itself; and failed to respond to substantial problems raised by commenters. For these and other reasons, its decision to apply the rule to investment companies was also arbitrary."); *id*. at 1152 ("By ducking serious evaluation of the costs that could be imposed upon companies from use of the rule by shareholders representing special interests, particularly union and government pension funds, we think the Commission acted arbitrarily."); *see also Sorenson Commc'ns Inc. v. FCC*, 765 F.3d 37, 50 (D.C. Cir. 2014) ("By adopting the new speed-of-answer metric without evidence of the cost to comply with it, the Commission acted arbitrarily and capriciously."); *Council of Parent Attorneys and Advocates, Inc. v. DeVos*, 365 F.Supp.3d 28, 53–54 (D.D.C. 2019) ("The Delay Regulation is also arbitrary and capricious because the government failed to consider all the relevant factors when considering the cost of the regulation. . . . Here, the government failed to adequately account for two relevant factors—the States' reliance cost and the cost of delay on children, parents, and society.").

seems to be based on a random, finger-in-the-air guess—not the standard that is legally required to impose a transformative regulatory action that departs from more than three decades of practice.

146. Defendants also received—but ignored—evidence that their own estimates of administrative costs were far lower than what will in fact occur. Through both the regular and Paperwork Reduction Act comment processes, Defendants received a variety of cost estimates from covered entities showing that compliance would require hiring staff or diverting significantly more resources than the two-hour-per-week estimate that was underlying Defendants' own cost estimate. As noted, for example, the AHA submitted comment letters identifying administrative costs for 340B hospitals. Likewise, Advocates for Community Health submitted a comment letter during the Paperwork Reduction Act process explaining that "47% of [community health centers] would need to hire 0.5 to 1 full-time equivalent (FTE), 36% estimate needing 1 to 2 FTEs, and 7% project needing more than two FTEs to meet the anticipated demand of reporting 340B rebate claims. Advocates for Cmty. Health, Ltr. to C. Britton (Nov. 12, 2025), available at https://advocatesforcommunityhealth.org/wp-content/uploads/2025/11/ACH-340B-Rebate-Model-Pilot-Program-Application-Implementation-and-Evaluation-OMB.pdf. Commenters also identified other administrative costs, such as additional payments to third-party vendors that would be necessary to comply with the requirements of the new program. Nevertheless, Defendants either ignored or failed to evaluate the benefits of the program against these costs.

147. *Second*, Defendants did not consider or address non-administrative monetary costs associated with a rebate program—the hundreds of millions of dollars' worth of upfront-payment costs imposed on covered entities. Again, HRSA knew these costs were critically important considerations. Even last year, HRSA repeatedly warned drug companies that under a 340B rebate model, "covered entities, including those which primarily serve rural and underserved populations,

would need to pay significantly higher prices on prescription drugs at the time of purchase." 340B_REBATES_000292, 340B_REBATES_000064 (both filed in the *Eli Lilly* Case, Dkt. 60-1). Likewise, HRSA noted concerns "that covered entities, operating with limited cash on hand would have difficulty finding sufficient funds to pay market prices for drugs at every purchase." *Id.* And yet, in announcing the present program, Defendants did not consider, balance, or explain those costs.

148. *Third*, the agency did not consider the non-monetary costs associated with the Rebate Program. For example, it nowhere calculated or considered the impact that the Rebate Program would have on patients and communities due to reduced access to care. Again, Defendants previously criticized drug companies' failure to "conduct[] an evaluation of the impact of this [rebate] proposal on the scope and breadth of health care access for patients served by affected covered entities." *Id.* Yet no such consideration or explanation of the costs to these patients took place prior to implementing the Defendants' Rebate Program.

149. On the other side of the ledger, the agency did not quantify or otherwise explain the benefits of the Rebate Program. Naturally, then, Defendants did not *balance* the (unexplained) benefits against the (undercounted) costs of the Rebate Program. That violates the APA. *E.g.*, *Chamber of Com. v. SEC*, 85 F.4th 760, 777 (5th Cir. 2023) ("[A]s part of that cost-benefit analysis, the agency must identify benefits that 'bear a rational relationship to the ... costs imposed.'" (quoting *Mexican Gulf Fishing*, 60 F.4th at 973)).

150. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, all in violation of the Administrative Procedure Act.

Count III – Administrative Procedure Act

(Order Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law – Failure to Consider Obvious and Less Burdensome Alternatives)

151. Plaintiffs repeat, re-allege, and incorporate the allegations in the preceding paragraphs.

152. Defendants' establishment and upcoming January 1, 2026 implementation of the 340B Rebate Model Pilot Program, as well as their approval of drug company applications to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

153. The Rebate Program is invalid because Defendants "fail[ed] to consider 'significant and viable and obvious alternatives.'" *Dist. Hosp. Partners, LP 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)). There are obvious alternatives to Defendants' decision to impose a rebate model to address a purported interest in deduplication of IRA and 340B Program discounts. Additionally, even if Defendants genuinely wanted to launch a "pilot" program to assess the costs and benefits of a rebate model for the 340B Program, there are numerous obvious and less-burdensome ways to deploy a true pilot program that would not impose hundreds of millions of dollars in costs across approximately 14,600 covered entities, including rural and other safety-net hospitals.

154. As noted in numerous letters Defendants received during comment period, there are obvious alternatives to addressing the concerns about duplicate discounts and diversion without needing to deploy a full rebate model. To take just one example, Plaintiff AHA proposed two versions of a "clearinghouse" that Defendants could have relied on to effectuate its goal of IRA/340B deduplication. Comment ID HRSA-2025-0001-0052. Despite formally adopting one of those "clearinghouses" *the day after* it approved drug company rebate program applications, Defendants did not adopt the less costly, less burdensome, perfectly functional, *co-existing* alternative for the rebate program.

155. Likewise, to the extent that Defendants wished to conduct a "pilot" program, Defendants could have designed a program that is much more limited in scope and burden. Defendants offered no reasons why they did not elect for a more constrained approach.

156. These alternatives were presented to the Defendants throughout the 1,100 comments that it received, but Defendants have not addressed any of these proposed alternatives.

157. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, all in violation of the Administrative Procedure Act.

Count IV – Administrative Procedure Act

(Rebate Program Is Substantively Unreasonable)

158. Plaintiffs repeat, re-allege, and incorporate the allegations in the preceding paragraphs.

159. Defendants' establishment and upcoming January 1, 2026 implementation of the 340B Rebate Model Pilot Program, as well as their approval of drug company applications to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

160. "In arbitrary and capricious cases, [courts] distinguish substantive unreasonableness claims from lack-of-reasoned-explanation claims. A substantive unreasonableness claim ordinarily is an argument that, given the facts, the agency exercised its discretion unreasonably. A decision that the agency's action was substantively unreasonable generally means that, on remand, the agency must exercise its discretion differently and reach a different bottom-line decision." *Multicultural Media, Telecom & Internet Council v. Fed. Commc'ns Comm'n*, 873 F.3d 932, 936 (D.C. Cir. 2017); *see also Penobscot Air Servs., Ltd. v. F.A.A.*, 164 F.3d 713, 719–20 (1st Cir. 1999) ("The reviewing court must 'look to see if the agency

decision, in the context of the record, is too unreasonable (given its statutory and factual context) for the law to permit it to stand.'" (quoting *Sierra Club v. Marsh*, 976 F.2d 763, 769 (1st Cir., 1992)).

161. The Rebate Program is substantively unreasonable because the hundreds of millions of dollars in monetary and non-monetary costs that HRSA would impose on covered entities (and their patients) could never outweigh the limited purported benefits that could come from it. The only justification HRSA has provided for the Rebate Program is that it will aid in deduplicating submissions under the IRA and the 340B Program. It was substantively unreasonable for Defendants to conclude that this narrow goal should cost $200 million or more. *E.g.*, *Thompson v. Clark*, 741 F.2d 401, 405 (D.C. Cir. 1984) ("Thus, if data in the regulatory flexibility analysis—or data anywhere else in the rulemaking record—demonstrates that the rule constitutes such an unreasonable assessment of social costs and benefits as to be arbitrary and capricious, . . . the rule cannot stand."); *see id.* ("For example, if a defective regulatory flexibility analysis caused an agency to underestimate the harm inflicted upon small business to such a degree that, when adjustment is made for the error, that harm clearly outweighs the claimed benefits of the rule, then the rule must be set aside. It is set aside, however, *not* because the regulatory flexibility analysis was defective, but because the mistaken premise reflected in the regulatory flexibility analysis deprives the rule of its required rational support, and thus causes it to violate—not any special obligations imposed by the Regulatory Flexibility Act—but the general legal requirement of reasoned, nonarbitrary decisionmaking[.]").

162. The Program is even more substantively unreasonable given that HRSA views the Rebate Program as a run-of-the-mill "pilot program" (which it is not). Even assuming that it is a typical pilot program, HRSA would force covered entities to bear at least $200 million (and, by

Plaintiffs' calculation, far more) in costs *to simply test* whether a rebate model should be used to deduplicate claims under the IRA and 340B Program. A true "pilot program" should not cost that much. That exorbitant price tag, particularly as compared to the benefits of the Rebate Program, falls outside the "zone of reasonableness." *Multicultural Media, Telecom & Internet Council*, 873 F.3d at 937.

163. The substantive unreasonableness of the Rebate Program is compounded by the fact that it contradicts the purposes of the 340B Program. Rather than allowing 340B hospitals 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), it requires them to spend millions of dollars on administrative costs and divert resources away from patient care. And rather than selecting a payment mechanism that is "most effective and most efficient from the standpoint of each type of "covered entity," *id.* at 16, it imposes one on 340B hospitals that is manifestly ineffective and inefficient. In these respects, HRSA "has failed to exercise its discretion in a reasoned manner" because the Rebate Program is "is unmoored from the purposes and concerns of the [340B] law[]." *Judulang v. Holder*, 565 U.S. 42, 53, 64 (2011).

164. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, all in violation of the Administrative Procedure Act.

Count V – Administrative Procedure Act

(Rebate Program Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law – Predetermined Result)

165. Plaintiffs repeat, re-allege, and incorporate the allegations in the preceding paragraphs.

166. Defendants' establishment and upcoming January 1, 2026 implementation of the 340B Rebate Model Pilot Program, as well as their approval of drug company applications to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

167. An agency acts unlawfully if it acts to seek a predetermined result, such that it is "unwilling or unable to rationally consider counterarguments." *New York v. U.S. Dep't of Com.*, 351 F. Supp. 3d 502, 663 (S.D.N.Y. 2019) (citation and internal quotation marks omitted), *aff'd in part, rev'd in part on other grounds*, 588 U.S. 752 (2019); *see Kravitz v. United States Dep't of Com.*, 366 F.Supp.3d 681, 750 (D. Md. 2019) (finding agency action to be unlawful where "Administrative Record ultimately shows that the citizenship question was the Secretary's predetermined answer to a question that he and his staff solicited"); *cf. Davis v. Mineta*, 302 F.3d 1104, 1112–13 (10th Cir. 2002) (granting relief on the ground that the agency had prejudged the decision at issue and conducted "an evidently *pro forma* public opportunity to comment"), *abrogated on other grounds by Dine Citizens Against Ruining our Env't v. Jewell*, 839 F.3d 1276 (10th Cir. 2016).

168. Defendants' actions demonstrate an unlawful commitment to a predetermined result. The following facts, among others, amply support that conclusion.

169. *First*, Defendants' total failure to respond to any comments identifying problems with the rebate program is strong evidence of their closed-mindedness.

170. *Second*, Defendant Engels' August 25, 2025 "Request for Emergency Approval" to OIRA evidences that Defendants were unalterably committed to acceding to drug company demands to "implement[] rebate models under 340B." Defendants' characterization of the January 1, 2026 effective date as an "emergency" shows that Defendants did not have an open mind about whether to move forward with this so-called "pilot" program. Agencies typically do not use pilot

programs to address "emergencies." And a true pilot program designed for testing the rebate model could have started at any time.

171. In reality, there was no real "emergency." Defendants' subsequent approval of an April 1, 2026 start-date for Novartis' rebate model severely undermines that assertion. Ultimately, Defendants' stated (but false) rationale that there was an "emergency" demonstrates that they were never going to reconsider their ill-advised and underdeveloped Rebate Program.

172. It is telling, moreover, that the "Request for Emergency Approval" was exclusively focused on what *drug companies* wanted. For example, Defendant Engels noted: "[i]f HRSA does not receive emergency approval, then manufacturers may argue that they do not have the tools they need to effectuate nonduplication of the MFP and the 340B discount." By contrast, at no point in Defendant Engels' "Request for Emergency Approval" did he indicate that Defendants had any concern for the views of *other regulated entities* like hospitals and health systems. Again, this indicates that Defendants were unalterably committed to acceding to *drug company* demands for a rebate model, no matter how many problems or reasonable alternatives *covered entities* identified.

173. *Third*, Defendants approved nine drug company applications *weeks before* the Paperwork Reduction Act comment period had even closed. This, too, is powerful evidence that cost was no object. Defendants were going to proceed with their predetermined Rebate Program no matter the cost or burden on covered entities.

174. This evidence proves that Defendants conducted a *pro forma* solicitation of public comments but, in reality, were unwilling to rationally consider counterarguments to their predetermined Rebate Program.

175. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, all in violation of the Administrative Procedure Act.

Prayer for Relief

Wherefore, Plaintiffs respectfully request that this Court declare that the 340B Rebate Model Pilot Program is unlawful; "set aside" the 340B Rebate Model Pilot Program 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 is permanently enjoined as unlawful and invalid;

B. Defendants are enjoined from implementing or giving effect to the Rebate Program in any way; and

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

Dated: December 1, 2025

Respectfully submitted,

/s/ Melissa A. Hewey

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