

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION,
et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., Secretary of the U.S.
Department of Health and Human Services, *et al.*,

Defendants.

Case No. 26-cv-00515

**CONSENT MOTION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF OF 340B
HEALTH, AMERICA'S ESSENTIAL HOSPITALS, ASSOCIATION OF AMERICAN
MEDICAL COLLEGES AND CHILDREN'S HOSPITAL ASSOCIATION IN SUPPORT
OF PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER**

Edward MacColl
THOMPSON, MACCOLL & BASS, LLC
15 Monument Square, 4th Floor
Portland, Maine 04101
Tel: (207) 774-7600
emaccoll@thomport.com

Counsel of Record

William B. Schultz*
Monica F. Sharma*
ZUCKERMAN SPAEDER LLP
2100 L Street NW, Suite 400
Washington, DC 20037
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
msharma@zuckerman.com

**pro hac vice application forthcoming*

Proposed *Amici Curiae* 340B Health, America's Essential Hospitals, Association of American Medical Colleges, and National Association of Children's Hospitals, Inc., d/b/a Children's Hospital Association hereby move the Court for leave to submit their brief for the Court's consideration in support of Plaintiffs' Motion for Temporary Restraining Order (ECF No. 2). In support, *Amici* state and allege as follows:

1. This case raises important issues affecting matters of public health in this District.
2. *Amici* and their members have a strong interest in the resolution of the questions of law raised by the Plaintiffs' Complaint and Motion for Temporary Restraining Order, in the particulars set forth in their brief.
3. The participation of *Amici* will assist and be useful to the Court in its evaluation of those issues and will not result in unfair prejudice to any party.
4. Counsel for *Amici* has advised the parties of their intention to file this brief, and both parties consent to the filing of this *amicus* brief.
5. The proposed brief of *Amici* is attached to this Motion as Exhibit A.

WHEREFORE, *Amici Curiae* respectfully request that they be given leave to submit their brief in support of Plaintiffs' Motion for Temporary Restraining Order.

Dated: October 19, 2026

Respectfully submitted,

/s/ Edward MacColl

Edward MacColl
THOMPSON, MACCOLL & BASS, LLC
15 Monument Square, 4th Floor
Portland, Maine 04101
Tel: (207) 774-7600
emaccoll@thomport.com

Counsel of Record

William B. Schultz*
Monica F. Sharma*
ZUCKERMAN SPAEDER LLP
2100 L Street NW, Suite 400
Washington, DC 20037
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
msharma@zuckerman.com

Counsel for Amici Curiae

**pro hac vice application forthcoming*

CERTIFICATE OF SERVICE

I certify that on October 19, 2026, I caused the foregoing to be served via the Court's ECF filing system on all registered counsel of record.

/s/ Edward MacColl

Counsel for Amici Curiae

UNITED STATES DISTRICT COURT
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**BRIEF OF *AMICI CURIAE* 340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS,
ASSOCIATION OF AMERICAN MEDICAL COLLEGES, AND
CHILDREN'S HOSPITAL ASSOCIATION IN SUPPORT OF
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Edward MacColl
THOMPSON, MACCOLL & BASS, LLC
15 Monument Square, 4th Floor
Portland, Maine 04101
Tel: (207) 774-7600
emaccoll@thomport.com

Counsel of Record

William B. Schultz*
Monica F. Sharma*
ZUCKERMAN SPAEDER LLP
2100 L Street NW, Suite 400
Washington, DC 20037
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
msharma@zuckerman.com

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INTERESTS OF *AMICUS CURIAE*

340B Health is a trade association representing hospitals that participate in the federal 340B Program by virtue of serving a high percentage of low-income patients or being designated as critical access hospitals. On behalf of over 1,600 public and private nonprofit hospitals and health systems, 340B Health educates and advocates for 340B to support 340B hospitals in their mission to serve low income, underserved, and rural patients.

America's Essential Hospitals (AEH) is dedicated to high-quality care for all, including those who face social and financial barriers. Consistent with this safety-net mission, AEH's more than 400 members provide a disproportionate share of the nation's uncompensated care, with three-quarters of their patients uninsured or covered by Medicare or Medicaid.

The **Association of American Medical Colleges (AAMC)** is a nonprofit association dedicated to improving the health of people everywhere through medical education, clinical care, biomedical research, and community collaborations. Its members are all 163 U.S. medical schools accredited by the Liaison Committee on Medical Education; more than 400 academic health systems and teaching hospitals; and more than 70 academic societies. Nearly 90 percent of AAMC's member teaching hospitals participate in the 340B Program and rely heavily on the Program's upfront discounts to generate resources that are used to provide critical health care programs for their communities, including vulnerable populations in those communities.

The **National Association of Children's Hospitals, Inc., d/b/a Children's Hospital Association (CHA)** is the nation's leading advocate for children's health, uniting more than 200 children's hospitals to improve care and amplify impact. Through a unique combination of pediatric-specific expertise, data, and networking, CHA drives informed and actionable progress from care to policy.

Amici and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care. The upfront discounts provided by the 340B Program are essential to achieving this goal. The Rebate Program will require 340B Providers to spend considerably more to maintain drug inventories, diverting their limited resources and reducing the funds available to support their operations and provide essential services for their patients. *Amici* therefore have a strong interest in the entry of a preliminary injunction to enjoin the 340B Rebate Model Program.

INTRODUCTION

Defendants' latest iteration of the 340B Rebate Model Program (the Rebate Program or the Program) suffers from the same flaws as its 2025 predecessor. Despite this Court's finding that the Health Resources and Services Administration (HRSA or the Agency) "likely fail[ed] to consider and reasonably explain the impact of a rebate model on 340B hospitals," *Am. Hosp. Ass'n v. Kennedy*, 820 F. Supp. 3d 30, 37 (D. Me. 2025), in enacting the 2025 version of the Program, HRSA has again given short shrift to 340B Providers'¹ substantial reliance interests in the upfront discount system established over the 34-year operation of the 340B Program.²

In response to HRSA's Request for Information following the Court's injunction of the 2025 Program, 340B Health, AEH, AAMC, and CHA (collectively, *Amici*) submitted detailed comments to the Agency explaining the disastrous practical implications of allowing manufacturers to provide the requisite 340B discounts through rebates, which include *billions* of dollars in costs and the reduction or elimination of essential health services for underserved

¹ 340B Providers refers to "covered entit[ies]" as defined in the 340B statute. *See* 42 U.S.C. § 256b(a)(4).

² The 340B Program means the drug pricing program codified at § 340B, Public Health Service Act, 42 U.S.C. § 256b (1992).

communities.³ These efforts were in vain. The Rebate Program, as revised, is *more expansive* in scope, encompassing *eighteen* high-cost drugs produced by ten drug manufacturers so far.⁴ See Notice Regarding 340B Rebate Model Pilot Program, 91 Fed. Reg. 48883 (Aug. 3, 2026) (authorizing the inclusion of up to 25 drugs in the Rebate Program).

Defendants’ failure to meaningfully engage with *Amici*’s substantial concerns while rubberstamping the conclusions of drug manufacturers violates the Administrative Procedure Act (APA) for the reasons discussed in Plaintiffs’ Motion. This *amicus* brief explains why the Court should not credit any claim that the Rebate Program, as a purported “pilot” program, should be subject to a lesser standard of APA review—an argument that rests on an inapposite, decades-old, out-of-Circuit case that is at odds with longstanding Supreme Court precedent.

It also sets forth why Defendants’ implementation of the Rebate Program would have devastating consequences for 340B Providers and the communities they serve. Without question, the Rebate Program will impede the 340B Program’s goal of ensuring 340B Providers have sufficient cash flow to serve low-income patients and communities. Denying access to upfront discounts will force 340B Providers to spend significantly more to maintain drug inventories and to float drug companies (whose annual profits are in the billions) the difference between the full price of the 340B drug and the 340B discount price. In short, the Rebate Program will be catastrophic for 340B Providers and their patients.

³ See, e.g., 340B Health Letter regarding Request for Information: 340B Rebate Model Pilot Program (HHS Docket No. HRSA–2026–03042) (Apr. 20, 2026); AEH Letter regarding HRSA-2026-03042: Request for Information: 340B Rebate Model Pilot Program (Apr. 20, 2026); AAMC Letter regarding Request for Information: 340B Rebate Model Pilot Program (HRSA–2026–03042) (Apr. 20, 2026).

⁴ The drugs included in the Rebate Program are those that are subject to negotiated prices under the Inflation Reduction Act (IRA).

STATUTORY BACKGROUND

Congress enacted the 340B Program in 1992 to cap the amount that 340B Providers must pay for drugs that are prescribed to their patients. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011). The statute was intended to curb the significant drug price increases that followed the Omnibus Budget Reconciliation Act of 1990, which required manufacturers to offer rebates for Medicaid drugs that would match their lowest prices, or “best prices,” offered to other purchasers. The House Committee on Veterans’ Affairs found that manufacturers had significantly increased their prices to reduce the financial impact of the new Medicaid rebates on their profits. H.R. Rep. No. 102-384(I) (1991), 1991 WL 255976. The 340B statute was passed to require manufacturers to pass on the value of the new Medicaid rebates to safety net hospitals, community clinics, and certain other health providers. 137 Cong. Rec. E3,138-02 (daily ed. Sept. 24, 1991) (statement of Rep. Wyden), 1991 WL 187877. Congress’s intent was to “reduce the costs of operations” for 340B Providers and to allow them to “stretch scarce Federal resources as far as possible” so that they could reach more eligible patients. H.R. Rep. No. 102-384(II), at 12, 22 (1992), 1992 WL 239341.

Under the 340B Program, drug manufacturers enter into agreements with the Secretary of the Department of Health and Human Services (HHS) known as Pharmaceutical Pricing Agreements (PPAs). 42 U.S.C. § 256b(a)(1). PPAs reiterate the statutory formula through which the prices for covered drugs are calculated: the average manufacturer price (AMP) as understood under the Social Security Act, less a rebate percentage, which is determined through a formula set out in the 340B statute using calculations made in the prior quarter under the Medicaid Drug Rebate Program (MDRP). *Id.* § 256b(a)(1), (a)(2)(A).⁵ Since the inception of the 340B Program,

⁵ The minimum amount of the discount is the greater of: (a) the “minimum [statutory] rebate percentage,” currently either 23.1, 17.1 or 13 percent depending on the type of drug; or (b) the difference between AMP and “the lowest

drug manufacturers have met their price reduction obligations under the 340B statute and PPAs through up-front discounts in the cost of covered drugs. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Rebate Option, 62 Fed. Reg. 45823, 45824 (Aug. 29, 1997).⁶

The 340B statute also lays out a comprehensive scheme to ensure program integrity through HRSA's supervision. It allows manufacturers and HRSA to audit 340B Providers to ensure compliance with the statutory prohibition on diversion (selling a 340B drug to an ineligible patient). The Secretary has also implemented a policy to prevent Medicaid duplicate discounts that requires 340B Providers to report their Medicaid billing numbers to HRSA if they use 340B for Medicaid patients covered under a Medicaid fee-for-service program. 42 U.S.C. § 256b(a)(5)(A)–(C); Notice Regarding the Section 340B Drug Pricing Program—Program Guidance Clarification, 65 Fed. Reg. 13983 (Mar. 15, 2000); *see also Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 456 (D.C. Cir. 2024). The Secretary may impose various sanctions on 340B Providers for violations found through an audit. 42 U.S.C. § 256b(a)(5)(D); *see also Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 700 (3d Cir. 2023). Through the Administrative Dispute Resolution (ADR) process, 340B Providers may bring complaints that they were overcharged for 340B drugs, and manufacturers (after conducting an audit) may bring complaints

price” the drug company has charged during the “rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity,” whichever is greater. The discount is further increased when AMP increases faster than the consumer price index for all urban consumers. 42 U.S.C. § 1396r-8(c)(1), (2).

⁶ HRSA recognized one exception to the general presumption that up-front price reductions are required under 340B. State AIDS Drug Assistance Programs (ADAPs) are permitted to participate in the 340B Program through rebates, rather than discounts, because they reimburse pharmacies for drugs and do not always purchase covered drugs directly. Because the ADAP drug purchasing mechanism prevented most ADAPs from accessing the benefits of 340B, in 1998 HRSA authorized ADAPs to utilize rebates as “an optional alternate means of accessing section 340B discount pricing” and made clear that it was doing so to meet “the unique needs” of ADAPs and was not authorizing a rebate option beyond ADAPs. Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992—Rebate Option, 63 Fed. Reg. 35239, 35239–41 (June 29, 1998). ADAPs voluntarily participate in the rebate program. In allowing ADAPs to access 340B pricing through rebates, HRSA cautioned manufacturers that they may not “condition a rebate contract or agreement upon . . . entities’ compliance with the provisions of section 340B.” *Id.* at 35239.

that 340B Providers are violating the prohibition on diversion or not complying with their obligations to prevent duplicate discounts. 42 U.S.C. § 256b(d)(3).

ARGUMENT

I. THE REBATE PROGRAM SHOULD NOT BE SUBJECT TO A MORE FORGIVING STANDARD OF REVIEW

In moving the First Circuit to stay the injunction of the 2025 Program, Defendants argued that their creation of the 2025 Rebate Program required “less justification” purely because it was (allegedly) a “pilot” program.⁷ See Mot. for Stay at 12-13, *Am. Hosp. Ass’n v. Kennedy*, Case No. 25-2236 (1st Cir. Dec. 30, 2025). This argument is meritless, and any attempt to resurrect it here should be summarily rejected.

To start, Defendants’ argument flies in the face of settled APA principles based on a misreading of a fifty-year-old, out-of-circuit case. See *id.* (citing *Aguayo v. Richardson*, 473 F.2d 1090 (2d Cir. 1973), *overruled on other grounds*, *Defending Ed. v. Croton-Harmon Union Free Sch. Dist.*, --- F.4th ----, 2025 WL 5281079 (2d Cir. Apr. 22, 2025)). That an agency must “articulate a satisfactory explanation for its action” is a fundamental tenet of administrative law, as recognized in the Supreme Court’s seminal (post-*Aguayo*) decision in *Motor Vehicle Manufacturers Association of the United States, Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 43 (1983). Further, unlike the statute at issue in *Aguayo*, the 340B statute does not explicitly authorize pilot programs. Even if it did, the Rebate Program, which has no end date and binds *all* 340B entities (to their detriment), cannot be characterized as merely a “limited data-gathering exercise.” Mot. for Stay at 13, *Am. Hosp. Ass’n v. Kennedy*, Case No. 25-2236 (1st Cir.

⁷ The First Circuit concluded that Defendants had waived this argument. See *Am. Hosp. Ass’n v. Kennedy*, 164 F.4th 28, 36 (1st Cir. 2026).

Dec. 30, 2025). As such, Defendants’ decision to implement the Rebate Program does not require “less justification” than any other agency action under the APA. *Id.*

A. *Aguayo* Does Not Support Defendants’ Position.

1. *Aguayo Did Not Announce a General Lesser Standard of Judicial Review For Pilot Programs.*

Defendants’ suggestion that an agency’s decision to greenlight a pilot program is subject to a lower standard of judicial review rests on a fundamental misreading of the Second Circuit’s decision in *Aguayo*. See Mot. for Stay at 12–13, *Am. Hosp. Ass’n v. Kennedy*, Case No. 25-2236 (1st Cir. Dec. 30, 2025) (citing *Aguayo*, 473 F.2d at 1103). *Aguayo* court held that the *Secretary* could apply a “lower threshold for persuasion when he is asked to approve a program that is avowedly experimental and has a fixed termination date.” See *Aguayo*, 473 U.S. at 1103. It did not hold that a *court* should apply a lower standard when determining whether agency action is arbitrary and capricious under the APA. See also Resp. Br. at 32, *Cochran v. Gresham*, Nos. 20-37, 20-38 (D.C. Cir. Feb. 18, 2021) (“*Aguayo* applied a ‘lower threshold for persuasion’ to the Secretary’s ultimate predictive determination only after confirming that the record reflected ‘a consideration of the relevant factors.’”). This “lower threshold” did not obviate the need for the Agency in *Aguayo* to consider relevant factors and, significantly, did not apply to “purely legal issues.” *Aguayo*, 473 U.S. at 1103; *id.* at 1106 (“We are satisfied that the materials before the Secretary sufficed for ‘a consideration of the relevant factors’ by him . . .”). Accordingly, *Aguayo* is of little value here.

2. *Aguayo Pre-Dates State Farm.*

Even if *Aguayo* could be read as Defendants claim (it cannot), it would run afoul of the Supreme Court’s holding in *State Farm*, 463 U.S. at 43.⁸ In that case, which post-dates *Aguayo*, the Supreme Court held that the APA requires an agency to “examine the relevant data and articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made.’” *State Farm*, 463 U.S. at 43 (citation omitted). Since *State Farm*, it has been black-letter law that “[a]n agency action qualifies as ‘arbitrary’ or ‘capricious’ if it is not ‘reasonable and reasonably explained.’” *Ohio v. Env’t Prot. Agency*, 603 U.S. 279, 292 (2024) (citation omitted). Defendants did not contend, nor could they, that the Supreme Court has embraced a lower standard of review for all pilot programs. *Cf. State Farm*, 463 U.S. at 42 (“[T]he direction in which an agency chooses to move does not alter the standard of judicial review established by law.”); *California v. U.S. Dep’t of Educ.*, 132 F.4th 92, 98 (1st Cir. 2025) (“The APA’s arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained.” (citation omitted)).

B. Neither the 340B Statute Nor Its Implementing Regulations Explicitly Authorize Test or Pilot Programs like the Rebate Program.

Equally damaging to Defendants’ argument is the fact that the 340B statute is silent as to pilot programs, *see* 42 U.S.C. § 256b—assuming *arguendo* that the Rebate Program qualifies as a limited pilot. This silence is legally significant.

Other statutory schemes, including the Social Security Act at issue in *Aguayo*, specifically authorize agencies to develop and implement pilot projects. *See, e.g.*, 42 U.S.C. § 1315(a)

⁸ While the Third Circuit cited *Aguayo* approvingly in a post-*State Farm* decision, it did so only in the limited context of Section 1315(a) waivers. *See C.K. v. New Jersey Dep’t of Health & Hum. Servs.*, 92 F.3d 171, 183 (3d Cir. 1996) (“We find *Aguayo* persuasive, and agree generally with that court’s statement of *the proper standard of review of section 1315(a) waivers* under the APA.” (emphasis added)). *But see Stewart v. Azar*, 313 F. Supp. 3d 237, 259–60 (D.D.C. 2018) (applying standard APA review as articulated in *State Farm* in the waiver context).

(authorizing the Secretary of Health and Human Services to waive compliance with certain Medicaid requirements “to the extent and for the period he finds necessary to enable such State or States to carry out” “experimental, pilot, or demonstration” projects); 2 U.S.C. § 1315a(b)(1) (“[T]he [Center for Medicare and Medicaid Innovation] shall test payment and service delivery models”); 5 U.S.C. § 4702(1) (U.S. Office of Personnel Management shall “establish and maintain . . . research programs to study improved methods and technologies in Federal personnel management”); *id.* at § 4703(a) (“[T]he Office of Personnel Management may . . . conduct and evaluate demonstration projects.”).⁹ The “lower threshold” discussion in *Aguayo* arose in a specific context that does not exist here: a legal regime authorizing the Secretary to approve waivers for pilot or demonstration projects that, “in the judgment of the Secretary,” furthered the statute’s goals. 42 U.S.C. § 1315(a); *see also* 42 C.F.R. § 431.416(d)(2) (providing that “CMS will review and consider all comments . . . but will not provide written responses to public comments” for Section 1115 projects).

As the above examples show, “Congress knows how to [authorize pilot programs] when it so chooses.” *Brito v. Garland*, 22 F.4th 240, 251 (1st Cir. 2021) (declining to read in a prohibition against declaratory relief in the face of statutory silence). Even if statutorily authorized pilot programs required less justification under the APA (they do not), the fact that Congress opted not to explicitly authorize experimental programs with respect to the 340B statute suggests that a lesser standard should not apply in the instant case. *Cf. Custis v. United States*, 511 U.S. 485, 492 (1994) (finding that Congress’s inclusion of certain language in one statute and “omission of similar language” in another was legally significant).

⁹ *See also, e.g.*, 20 C.F.R. § 641.610 (“[Agency] may enter into agreements with States, public agencies, nonprofit private organizations, or private business concerns, as may be necessary, to conduct pilot, demonstration, and evaluation projects” pursuant to the Senior Community Service Employment Program); 20 C.F.R. § 686.565 (authorizing “experimental, research and demonstration projects related to the Job Corps program”).

C. The Rebate Program is Not a “Test” or “Pilot.”

But even if the 340B statute authorized pilot programs, a lesser standard of review would still be improper here because the Rebate Program is not a “pilot” in function or effect. First, unlike the programs in *Aguayo*, it does not have “a fixed termination date.” *Contra Aguayo*, 473 F.2d at 1103 (emphasizing that the program at issue was “avowedly experimental and *ha[d] a fixed termination date*” (emphasis added)); *id.* at 1106 (noting “the Secretary could properly give weight to the fact that the programs were of *limited duration*” (emphasis added)). While HRSA intends to publish an evaluation of the Rebate Program in April 2028 following the “conclusion of the first year of Pilot operations,” it does not indicate that the Program will cease during the pendency of that evaluation—or ever. *See 340B Rebate Model Pilot Program*, HRSA, <https://www.hrsa.gov/opa/340b-model-pilot-program> (last visited Oct. 4, 2026).

Second, the Rebate Program is *mandatory* for *all* covered entities. 91 Fed. Reg. at 48,901. No covered entity has opted to be part of this so-called “pilot” program, yet every covered entity will be forced to participate. Worse still, it is the covered entities—not the manufacturers, all of whom have *elected* to participate in the Rebate Program—that will be forced to bear the burden of substantial administrative and other costs from this purported “limited data-gathering exercise.” Labeling the Rebate Program a “pilot” does not a pilot program make.

For all these reasons, the Rebate Program should be subject to standard APA review as articulated in *State Farm*.

II. THE REBATE PROGRAM POSES IMMEDIATE THREATS OF IRREPARABLE HARM TO PATIENT ACCESS TO ESSENTIAL HEALTH CARE SERVICES.

The 340B Program is comprised of safety-net providers that depend on critical statutory savings on eligible drugs to provide care that is often uncompensated or undercompensated. Hospitals may participate in 340B only if they can demonstrate that they serve a disproportionate

number of low-income patients or that they are designated by Medicare as “critical access” hospitals. In 2020, for example, the share of services to low-income patients by 340B Hospitals¹⁰ was 40.6% compared to 26.2% for non-340B hospitals.¹¹ 340B Hospitals offer significantly more services compared to their non-340B counterparts, including specialized services and essential community services that address broader health, wellness and social needs.¹² 340B Hospitals provide three-quarters (75%) of all hospital care for Medicaid patients, a program known for low reimbursement that does not typically cover the cost of care, and two-thirds (67%) of hospital uncompensated and unreimbursed care.¹³ 340B Hospitals further account for 80% of hospitals offering burn care and transplants of lung, liver, and bone marrow, all of which are relatively unprofitable services.¹⁴ Not surprisingly, 340B Hospitals have substantially lower—and often negative—operating margins compared to non-340B providers.¹⁵

The discounts provided under the 340B Program allow 340B Providers to provide care to low-income and vulnerable patients. The Government Accountability Office (GAO) has explained that “the up-front savings [340B Providers] realized on the cost of drugs, allowed [340B Providers] to support their missions by maintaining services and lowering medication costs for patients, which

¹⁰ 340B Hospitals refers to hospitals that qualify as “covered entit[ies]” as defined in the 340B statute. *See* 42 U.S.C. § 256b(a)(4).

¹¹ Allen Dobson et al., *340B DSH Hospitals Serve Higher Share of Patients with Low Incomes*, Dobson DaVanzo Health Economics Consulting 21 (Sept. 26, 2022), https://www.340bhealth.org/files/340B_and_Low_Income_Populations_Report_2022_FINAL.pdf.

¹² *Id.* at 14.

¹³ *Id.* at 7.

¹⁴ *Id.* at 15.

¹⁵ Steven Heath et al., *340B DSH Hospitals Increased Uncompensated Care in 2020 Despite Significant Financial Stress*, Dobson DaVanzo Health Economics Consulting (2022), https://www.340bhealth.org/files/Dobson_DaVanzo_Op_Margins_and_UC_FINAL.pdf; Am. Hosp. Ass’n, *Fact Sheet: 340B Drug Pricing Program: Fact vs. Fiction 3* (Mar. 2021), <https://www.aha.org/2021-03-15-setting-record-straight-340b-fact-vs-fiction>.

is consistent with the purpose of the program.”¹⁶ Moreover, the GAO found that 340B Providers “used the 340B revenue generated by certain patients to offset losses incurred from other patients, which helped support the financial stability of the organization and allowed them to maintain services.”¹⁷ As a result, 340B Providers “serve more patients and . . . provide services that they might not have otherwise provided.”¹⁸

As a result of the financial support from the 340B Program, 340B Hospitals have increased the amount of net patient revenue spent on uncompensated and unreimbursed care when compared to non-340B hospitals, with the gap widening from 17.5% higher for 340B Hospitals in 2019, to 29.1% higher in 2022.¹⁹ Similarly, in 2022 alone, 340B Hospitals provided nearly \$100 billion in community benefits, a nearly 47% increase from 2019.²⁰

As Plaintiffs have explained, 340B Providers have already halted critical hospital projects in anticipation of having to “float” costs to drug manufacturers. Eliminating these projects and affiliated services inflicts immediate and irreparable harm to patients, which no subsequent restoration of dollars can undo.²¹ Nor will 340B Providers be able to recoup as damages the time

¹⁶ Report to Congressional Committees, GAO-11-836, *Drug Pricing, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO 17-18 (Sept. 2011), <https://www.gao.gov/assets/gao-11-836.pdf>.

¹⁷ *Id.* at 17.

¹⁸ *Id.*

¹⁹ KNG Health Consulting LLC, *340B Hospitals Increased Contributions to Uncompensated and Unreimbursed Care During the Pandemic 2* (Feb. 2025), 340B Health, https://www.340bhealth.org/files/KNG_Health_Final_Report_February_2025.pdf.

²⁰ Am. Hosp. Ass’n, *Fact Sheet: 340B Drug Pricing Program: Fact vs. Fiction 2* (Oct. 2025), <https://www.aha.org/2021-03-15-setting-record-straight-340b-fact-vs-fiction>.

²¹ 340B Health, *Summary of 340B Health Survey Results: Impact of the 340B Rebate Pilot on 340B Hospitals* (Sept. 8, 2025), https://www.340bhealth.org/files/FINAL-Summary-of-340B-Health-Survey-Results.docx_9_.8.25.pdf.

and money that they will be (and are being) forced to spend on staffing and technological infrastructure in the interim even if the Rebate Program is, as it should be, ultimately invalidated.²²

In addition to supporting safety-net facilities and their patients, 340B plays an important role in curbing drug price increases for all Americans, resulting in savings of \$7 billion from 2013 to 2017 for Medicare Part D alone.²³ The more drug companies can limit the number of their drugs that are subject to 340B, the easier it is for them to reap the benefits of sky-high price increases.

Furthermore, hospitals—as stated in a 340B Health survey—anticipate that the Rebate Program will harm hospitals and patients in the following ways:²⁴

- Reducing the availability of discounted or free medications to patients (58%);
- Reducing the ability to keep hospital doors open (57%);
- Reducing the provision of discounted and/or free drugs at any pharmacy location(s) (68%);
- Reducing access to patient care services for low-income and/or rural patients (89%); and
- Reducing the provision of uncompensated care (72%) and charity care (74%).

III. HRSA FAILED TO REASONABLY ASSESS THE SIGNIFICANT COSTS AND BURDENS THAT THE REBATE MODEL WILL IMPOSE ON 340B PROVIDERS.

HRSA failed to appropriately weigh costs and benefits, violating the APA twice over. As Plaintiffs explain in detail, Defendants unreasonably dismissed significant concerns that 340B

²² See, e.g., AEH Letter regarding Information Collection Request: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW (July 13, 2026) at 4, <https://essentialhospitals.org/wp-content/uploads/2026/07/July-2026-Rebate-ICR-Response.pdf> (“One member hospital already has spent more than 165 staff hours preparing for rebate model compliance—exceeding HRSA’s estimated annual burden before the pilot has even begun.”); Compl. ¶¶ 70–79, 84, ECF No. 1.

²³ Sean Dickson, *Association Between the Percentage of US Drug Sales Subject to Inflation Penalties and the Extent of Drug Price Increases*, JAMA Open 1 (Sept. 11, 2020), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2770540>.

²⁴ 340B Health, *Summary of 340B Health Survey Results: Impact of the 340B Rebate Pilot on 340B Hospitals* 1, 3 (Sept. 8, 2025), https://www.340bhealth.org/files/FINAL-Summary-of-340B-Health-Survey-Results.docx_9_8.25.pdf.

Providers and others have raised about the costs and burdens of the Rebate Program in response to HRSA's Request for Information.²⁵ *See also* Compl. ¶¶ 228–48, ECF No. 1.²⁶

And with such significant costs inflicted on 340B Providers, the Rebate Program is, as before, substantively unreasonable such that any “call for judicial deference . . . rings hollow.” *Am. Hosp. Ass’n v. Kennedy*, 820 F. Supp. 3d at 44. Congress intended that HHS select a payment mechanism that is “most effective and most efficient from the standpoint of each type of ‘covered entity,’” H.R. Rep. No. 102-384(II), at 16 (1992), 1992 WL 239341, but the costs that 340B Providers highlighted demonstrate just how impossibly ineffective and inefficient the rebate model will be. An agency action that is so “unmoored from the purposes and concerns of the . . . law[]” simply cannot survive APA scrutiny. *Judulang v. Holder*, 565 U.S. 42, 64 (2011).

Safety-net hospitals will face significant challenges during the period they must “float” the savings from the 340B discounts—even if brief and even if rebates are ultimately received. Waiting 10 days to receive rebates after data submission, as contemplated in the Rebate Program, would tie up critical resources for 340B Hospitals, forcing 58% of hospital survey respondents to reduce the availability of discounted or free medications and half of respondents to reduce access to patient care for low-income and/or rural patients.²⁷ To make matters worse, hospitals have little to

²⁵ *See, e.g.*, 340B Health Letter regarding Request for Information: 340B Rebate Model Pilot Program (HHS Docket No. HRSA– 2026–03042) §§ II–III (Apr. 20, 2026); AAMC Letter regarding Request for Information: 340B Rebate Model Pilot Program (HRSA–2026–03042) at 6–10 (Apr. 20, 2026).

²⁶ For instance, despite recognizing that a “significant number of commenters raised concerns about the burden” that data submission requirements would impose on 340B Providers, HRSA maintained its gross underestimation of a mere *five hours* of burden per response. 91 Fed. Reg. 35989–90 (June 15, 2026). The actual burden is likely to be much higher. *See* AAMC Letter regarding Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-XXXX (Apr. 22, 2026) at 2 (“AMC member hospitals expect their staff to spend at least 25 to 40 hours a week to submit claims data to a third-party platform, which totals 1300 to 2080 hours annually per hospital and is five to eight times higher than HRSA’s estimate.”).

²⁷ 340B Health, *Summary of 340B Health Survey Results: Impact of the 340B Rebate Pilot on 340B Hospitals* 1, 3 (Sept. 8, 2025), https://www.340bhealth.org/files/FINAL-Summary-of-340B-Health-Survey-Results.docx_9_.8.25.pdf.

no control over the length of the waiting period under the Rebate Program. In practice, the time between purchasing a drug at the wholesale acquisition cost (WAC) and receiving the rebate for that drug will often be much longer than 10 days because hospitals cannot request a rebate until the drug is dispensed to a 340B patient and the claims data is submitted. Accordingly, almost all surveyed hospitals (95%) are concerned that this delay will meaningfully increase their cash-flow challenges.²⁸ These challenges will be compounded by the substantial additional costs associated with information technology, compliance, rebate reconciliation for millions of claims, and third-party vendors that 340B Hospitals will have to absorb in order to access discounted drugs.²⁹

HRSA did not adequately assess the costs and administrative burdens that the Rebate Program would impose on 340B Providers. Parts of HRSA's explanation for why it was not increasing its burden estimate are virtually identical to assertions made by nearly all of the drug manufacturers that submitted comments to the Agency regarding the Rebate Program.³⁰ At least 17 manufacturers and two rebate vendors asserted in their rebate comments that the Rebate Program would impose minimal burdens on 340B Providers because Providers have existing systems that could support rebate reporting and already maintain the required data elements—assertions that were specifically refuted by scores of 340B Hospitals.³¹ Of the more than 250 hospitals that commented, virtually all said that rebate reporting would not be easy and that managing the rebate process would impose significant costs.³²

²⁸ *Id.* at 2.

²⁹ AAMC Letter regarding Request for Information: 340B Rebate Model Pilot Program (HRSA–2026–03042) (Apr. 20, 2026) at 2.

³⁰ *See* 340B Health, 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906–NEW, July 16, 2026, https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202606-0906-001

³¹ *Id.* at 3 n.10, 5, 6 n.25.

³² *Id.* at 5.

Further, though HRSA outlined some criteria for manufacturer plans under the Rebate Program, manufacturers that provide “detailed justification” may “exceed or go beyond” those criteria.³³ And at least one drug manufacturer appears to have taken advantage of this so far. Although HRSA has outlined certain bases on which a manufacturer may *not* deny rebate claims, this manufacturer’s HRSA-approved rebate plan indicates that it plans to deny rebates for claims on one of these prohibited bases.³⁴ This raises serious concerns under the APA.

IV. **THE REBATE PROGRAM IS NOT NECESSARY TO PREVENT DUPLICATE DISCOUNTS.**

HRSA’s justification for its Rebate Program rests on a flawed premise that the Program is needed to enforce the 340B Statute’s prohibition against duplicate discounts. Under the Medicaid Drug Rebate Program (MDRP), states are entitled to collect a rebate from manufacturers on certain Medicaid drugs. 42 U.S.C. § 1396r-8. The duplicate discount provision in the 340B Statute is designed to ensure that, when Providers dispense 340B drugs to Medicaid recipients, manufacturers are not stuck providing both a 340B discount (to the 340B Provider) and a Medicaid Rebate (to the state Medicaid agency). 42 U.S.C. § 1396r-8; 42 U.S.C. § 256b(a)(5)(A)(i). If the manufacturer were to pay a rebate to the state under the MDRP for a drug that had been purchased at the 340B discount price, then it will have paid a “duplicate discount.” *See id.*³⁵

³³ 91 Fed. Reg. at 48902 (“Manufacturer plans that exceed or go beyond these criteria must include detailed justification and will be subject to additional levels of review by HRSA/ OPA prior to approval.”).

³⁴ Compare *id.* at 48903 (stating that “[r]ebates *may not be denied* for perceived lack of WAC purchases. If a manufacturer has concerns regarding . . . insufficient WAC purchases to support rebate requests, the manufacturer must raise those concerns directly with HRSA/OPA or utilize the 340B statutory mechanisms, such as audits and administrative dispute resolution, for addressing such issues” (emphasis added)) to AbbVie Inc. 340B Rebate Model Pilot Plan, 4, <https://www.hrsa.gov/sites/default/files/hrsa/opa/imbruvica-abbvie-340b-rebate-model-pilot-program-policy.pdf> (stating that “AbbVie will continually monitor instances where non-WAC purchases were used for 340B rebate submission [and] *deny* any such rebate requests” (emphasis added)).

³⁵ It is not true that 340B Providers sometimes receive the benefit of two discounts because 340B Providers never receive a Medicaid Rebate; state Medicaid agencies do. 42 U.S.C. § 1396r-8. The duplicate discounts occur when the manufacturer is both selling a drug at a discount and providing the state a rebate. 42 U.S.C. § 256b(a)(5).

For Medicaid Fee-for-Service (FFS) claims, the law is clear: under the 340B Statute, the Secretary is required to develop a mechanism to prevent duplicate discounts. 42 U.S.C. § 256b(a)(5)(A)(ii). The Secretary’s chosen mechanism requires 340B Providers to list their billing numbers on HRSA’s Medicaid Exclusion File (MEF) so that state Medicaid agencies can exclude claims with those billing numbers from their rebate requests to manufacturers. *See Clarification on the Use of Medicaid Exclusion File*, HRSA (Dec. 12, 2014), <https://www.hrsa.gov/sites/default/files/hrsa/opa/clarification-medicaid-exclusion.pdf> (December 2014 MEF Clarification). The MEF helps states determine whether they should seek a Medicaid Rebate on a drug claim. *Id.* If the claim is made by a 340B Provider listed on the MEF (meaning they bought the drug at the 340B discount), then the state may not invoice or receive a Medicaid rebate from the manufacturer. *Id.* At least twenty-two states have created alternative methods to ensure that manufacturers are not providing duplicate discounts and do not rely on the MEF. U.S. Gov’t Accountability Off., GAO-20-212, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* (Jan. 2020), Appendix III, <https://bit.ly/3ZG0ctH>.

HRSA audits 340B Providers’ compliance with this mechanism. *See* December 2014 MEF Clarification. Failure to correctly list billing numbers on HRSA’s MEF results in a “duplicate discount” finding but, crucially, this is *not* evidence that a duplicate discount in fact occurred. Rather, it is only evidence that the Provider did not list its billing numbers correctly on HRSA’s MEF. HRSA will not investigate to determine whether a duplicate discount has actually occurred and will not downgrade the audit finding unless the Provider can provide evidence from the relevant state Medicaid agency showing that duplicate discounts did not occur. Over two-thirds of the “duplicate discount findings” issued in 2022 were changed to “MEF” errors after 340B

Providers challenged those findings using letters from Medicaid agencies that confirmed that manufacturers did not actually pay duplicate discounts in those cases, despite an error appearing on the 340B Providers' MEF. *See* HRSA Program Integrity, FY 22 Audit Results, <https://www.hrsa.gov/opa/program-integrity/fy-22-audit-results>.

Medicaid managed care claims are treated differently than FFS claims insofar as state Medicaid programs are responsible for preventing duplicate discounts—not Providers. Pursuant to the Medicaid statute, the Centers for Medicare & Medicaid Services (CMS) directs states to exclude 340B managed care claims from their rebate requests. *See* 42 U.S.C § 1396r-8(j)(1)(A); 42 C.F.R. § 438.3(s)(3); *see also* *Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630 (D.D.C. May 15, 2025), at *9 n.3 (“The responsibility for preventing duplications for managed care organizations falls to state Medicaid agencies.”). 340B Providers have no role in preventing managed care organizations from improperly claiming rebates on 340B claims.

Further, CMS has recently asked 340B Providers to voluntarily provide data that could be used to implement the Inflation Reduction Act's (IRA's) non-duplication provision, which bars Providers from receiving discounts under both 340B and the IRA. Yet CMS is refusing to use that data for purposes of implementing the IRA's non-duplication provisions.³⁶ There is no reason for the Agency to mandate that 340B Providers submit data to manufacturers under the Rebate Program when CMS can use the data it is collecting from Providers to prevent duplication under the IRA.

³⁶ *See* 91 Fed. Reg. 43842, 44009 (July 16, 2026) (“[W]e adopted our proposal to establish a voluntary Medicare Part D Claims Data 340B Repository (‘340B repository’) to collect data about 340B units voluntarily submitted by covered entities (90 FR 49750)”).

V. **THE REBATE PROGRAM UNDERMINES THE PURPOSE OF THE 340B PROGRAM.**

HRSA's Rebate Program disturbs the way the 340B Program has operated for more than 30 years: as an upfront discount program (except for ADAPs, *see supra* 5 n.6). Currently, the 340B Program allows safety-net providers to purchase drugs at a discount and charge insurers the same rates charged by non-340B providers. In this way, the 340B Program generates savings for covered entities amounting to the difference between the 340B price and the price they would have otherwise paid.

By allowing drug manufacturers to provide the 340B statutory drug discounts through backend rebates, the Rebate Program effectively requires cash-strapped covered entities to provide interest-free loans to drug manufacturers by purchasing 18 high-cost medications at significantly elevated wholesale acquisition cost prices and waiting for rebates reimbursing the difference between that price and the 340B discount on the backend. By denying access to upfront discounts, the Rebate Program will require hospitals to spend considerably more to maintain drug inventories and, in effect, front the cost difference for pharmaceutical companies. This diversion of limited resources to already-profitable manufacturers directly reduces the funds available to 340B Providers to care for low-income, rural, and underserved patients and to support their operations. Such a shift would fundamentally undermine the purpose of the 340B Program, which Congress created to “reduce the costs of operation” for safety-net providers, allowing them to “stretch scarce Federal resources as far as possible” so that they could reach more eligible patients.³⁷

³⁷ See H.R. Rep. No. 102-384(II), at 12, 22 (1992), 1992 WL 239341.

CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for Temporary Restraining Order should be granted.

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Respectfully submitted,

/s/ Edward MacColl

Edward MacColl
THOMPSON, MACCOLL & BASS, LLC
15 Monument Square, 4th Floor
Portland, Maine 04101
Tel: (207) 774-7600
emaccoll@thomport.com

Counsel of Record

William B. Schultz*
Monica F. Sharma*
ZUCKERMAN SPAEDER LLP
2100 L Street NW, Suite 400
Washington, DC 20037
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
msharma@zuckerman.com

Counsel for Amici Curiae

** pro hac vice application forthcoming*

CERTIFICATE OF SERVICE

I certify that on October 19, 2026, I caused the foregoing to be served via the Court's ECF filing system on all registered counsel of record.

/s/ Edward MacColl

Counsel for Amici Curiae