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. 25-cv-600

BRIEF OF *AMICI CURIAE* 340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS, AND ASSOCIATION OF AMERICAN MEDICAL COLLEGES IN SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER

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INTEREST OF *AMICI CURIAE*

340B Health is a national, not-for-profit organization founded in 1993 to advocate for 340B hospitals—a vital part of the nation's healthcare safety net. 340B Health represents over 1,600 public and private nonprofit hospitals and health systems participating in the 340B program.

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 nearly 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 162 U.S. medical schools accredited by the Liaison Committee on Medical Education; nearly 500 academic health systems and teaching hospitals; and more than 70 academic societies. Many 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.

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. *Amici* therefore have a strong interest in the entry of a temporary restraining order to enjoin Defendants from allowing manufacturers to provide discounts through rebates through the "340B Rebate Model Pilot Program" (the Rebate Program or the Program).

As a result of their strong interest, 340B Health has participated in four cases now pending in the D.C. Circuit involving drug company challenges to Defendants' denial of proposals to implement rebate models before the Rebate Program was announced, *see Novartis Pharms. Corp. v. Kennedy*, No. 25-2553 (D.C. Cir.), and AEH has filed *amicus* briefs in such cases at the district court level and one in the D.C. Circuit.

INTRODUCTION

Since the inception of the 340B Program in 1992, drug manufacturers have satisfied their obligations under the 340B statute by allowing 340B Providers to purchase 340B drugs at the statutorily prescribed discount, which is what the law requires. In the fall of 2024, five drug companies suddenly announced—through press releases and lawsuits—that they would abandon their 30-year practice of complying with section 340B by providing discounts. They claimed that providing backend rebates would address perceived abuses in the payment system and were necessary to comply with their obligations under the Inflation Reduction Act.

Although Defendants initially responded by defending the prevailing upfront discount system, in July 2025, in a stunning about-face, they announced that they would roll out the Rebate Program. The Rebate Program allows the manufacturers of the 10 high-cost drugs subject to negotiated prices under the Inflation Reduction Act in 2026 to provide 340B pricing to covered entities through rebates.

The Rebate Program will thwart the 340B Program's goal of ensuring covered entities have sufficient cash flow to serve low-income patients and communities and ignores the substantial reliance interests of those covered entities established over the 33-year operation of the 340B program. Denying access to upfront discounts and allowing drug companies the discretion to reject claims for rebates means that 340B Providers would have to spend significantly more to maintain

their drug inventories and 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 other words, the Rebate Program effectively requires financially strapped 340B Providers to give highly lucrative drug manufacturers interest-free loans. This *amicus* brief sets forth why Defendants' implementation of the Rebate Program—if allowed to go forward—would entail catastrophic consequences for covered entities and the communities they serve.[1]

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), 137 Cong Rec E 3,138-02, at *E3,138-02 (Westlaw). 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 (1992), 1992 WL 239341.

[1] In addition to the irreparable harm described below, Plaintiffs' Motion plainly demonstrates that they are likely to succeed on the merits and are therefore entitled to a temporary restraining order.

Under the 340B Program, drug manufacturers enter into agreements with the Secretary 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).[2] Since the inception of the 340B Program, drug manufacturers have met their price reduction obligations under the 340B statute and PPAs through up-front price reductions 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).[3]

Beyond the most basic purpose of capping the cost of drugs for 340B Providers, the 340B statute lays out a comprehensive scheme through which drug manufacturers and 340B Providers participate in the 340B Program under the supervision of the Health Resources and Services Administration (HRSA) in HHS. For example, the 340B statute allows manufacturers and HRSA to audit 340B Providers to ensure compliance with the prohibition on diversion (selling a 340B

[2] 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 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).

[3] 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.

drug to an ineligible patient). The Secretary has also implemented a policy to prevent Medicaid duplicate discounts (wherein after selling a drug at the 340B discount, the manufacturer subsequently provides a Medicaid rebate on that same drug in response to a request from a State Medicaid agency) which 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 (March 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. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696, 700 (3d Cir. 2023). Through an 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 that 340B Providers are violating the prohibition on diversion or not complying with their requirements to prevent duplicate discounts. 42 U.S.C. § 256b(d)(3).

ARGUMENT

A. The Rebate Program Poses Immediate and Irreparable Threats to Patient Access to Essential Health Care and Services From 340B Providers.

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 low-income patients treated by 340B Hospitals was

40.6% compared to 26.2% for non-340B hospitals.[4] As a result, compared to their non-340B counterparts, 340B Hospitals offer significantly more un- or under-reimbursed essential community services, including those that address broader health, wellness, and social needs.[5] 340B Hospitals provide three-quarters (77%) 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.[6] 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.[7] Not surprisingly, 340B Providers have substantially lower—and often negative—operating margins compared to non-340B providers.[8]

The discounts provided under the 340B program allow 340B Hospitals 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 is consistent with the purpose of the program."[9] Moreover, the GAO found that 340B Providers "used the 340B revenue generated by certain patients to offset losses incurred from other patients,

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[4] 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.

[5] *Id.* at 14.

[6] *Id.* at 7.

[7] *Id*. at 15.

[8] 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.

[9] 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.

which helped support the financial stability of the organization and allowed them to maintain services."[10] As a result, 340B Providers "serve more patients and . . . provide services that they might not have otherwise provided."[11]

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.[12] Similarly, in 2022 alone, 340B Hospitals provided nearly $100 billion in community benefits, a nearly 47% increase from 2019.[13]

As Plaintiffs have explained, in anticipation of having to "float" millions of dollars to drug manufacturers, 340B Providers have already halted critical hospital projects to the detriment of patient care. Eliminating these projects and affiliated services inflicts immediate and irreparable harm to patients, which no subsequent restoration of dollars can undo.[14]

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.[15] The more drug companies can limit the number of their drugs subject to 340B, the easier it is for them to continue with sky-high price increases.

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[10] *Id.* at 17.

[11] *Id.*

[12] 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.

[13] 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.

[14] 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.

[15] 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.

Furthermore, hospitals—as stated in a 340B Health survey— anticipate that the Rebate Program will harm hospitals and patients in the following ways:[16]

- 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%).

B. HHS Failed to Consider the Significant Costs and Administrative Burdens that the Rebate Model Will Impose on 340B Providers.

HRSA's failure to appropriately weigh costs and benefits violates the APA twice over. For starters, Defendants ignored significant concerns raised by 340B Hospitals and other providers in response to HRSA's Rebate Program notice about the costs and burdens of the Program.[17] For instance, 340B Health shared findings with HRSA from a survey of over 400 covered entities that found that the average 340B Hospital would "float" $8.6 million to drug manufacturers pending receipt of the 340B discounts on the backend.[18] Defendants did not respond at all.

Those costs underscore the second basic administrative law failing here: with such significant costs inflicted on 340B Hospitals, this Rebate Program is "substantively unreasonable." *See* Compl. Count IV, ECF No. 1. 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.

[16] 340B Health, *Summary of 340B Health Survey Results: Impact of the 340B Rebate Pilot on 340B Hospitals* 3 (Sept. 8, 2025), https://www.340bhealth.org/files/FINAL-Summary-of-340B-Health-Survey-Results.docx_9_.8.25.pdf.

[17] *See, e.g.*, 340B Health Letter relating to 340B Rebate Pilot Program (HHS Docket No. HRSA-2025-14619) § III.A (Sept. 8, 2025), https://www.nachc.org/wp-content/uploads/2025/09/09_08_25_NACHC_340B-Rebate-Model-Pilot-Program-Comment-Letter.pdf; America's Essential Hospitals Letter relating to Program Notice: Application Process for the 340B Rebate Model Pilot Program, Docket No. HRSA–2025–14998 (Sept. 8, 2025), https://essentialhospitals.org/wp-content/uploads/2025/09/340B-Rebate-Model-Pilot-Program-nosig.pdf.

[18] 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

Rep. No. 102-384, pt. 2, at 12 (1992), but these costs demonstrate just how impossibly 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, 53 (2011)

Safety-net hospitals would face significant challenges in the time period they "float" the savings from the 340B discounts—even if the waiting period is brief and rebates are ultimately received. Waiting just 10 days to receive rebates after data submission would tie up critical resources for 340B Hospitals, forcing 58% of hospital respondents to 340B Health's survey 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.[19] To make matters worse, under the Rebate Program, hospitals have little to no control over the length of the waiting period. Although rebates would need to be paid within 10 days of a hospital's submission of claims data to the drug manufacturer, the time between purchasing at the wholesale acquisition cost (WAC) and receipt of the rebate will often be much longer. This is because the hospital cannot request a rebate until the drug is actually dispensed to a 340B patient and the claims data is submitted. Accordingly, almost all surveyed covered entities (95%) are concerned that the amount of time between purchases at WAC and when the drugs are ultimately dispensed will meaningfully increase the cash-flow challenges and harms imposed by the waiting period.[20]

Even worse, although the Rebate Program notice provides that manufacturers should not deny rebates "based on compliance concerns with diversion or Medicaid duplicate discounts," 90 Fed. Reg. 38165, 386166 (Aug. 7, 2025), the notice does not specify all the grounds on which manufacturers ***may*** deny rebates. In fact, a webinar given by HRSA to covered entities on

[19] *Id.*

[20] *Id.*

December 4, 2025 confirms that manufacturers may deny claims for "Other" reasons with a documented explanation.[21] This leaves room for manufacturers to deny rebates for a myriad of pretextual reasons as long as they provide one. This presents huge issues for covered entities because challenging denial decisions creates a massive hurdle for the providers. At the very least, HRSA's failure to provide a reasoned explanation for *all* of the reasons why a rebate may be denied, as well as its failure to provide adequate notice to regulated parties about the "other" reasons they could lose statutory discounts, raise serious concerns under the APA.

Further, HRSA's estimates of the costs of compliance for covered entities are based on incorrect and unsupported assumptions. HRSA has stated that it anticipates that covered entities will incur at least $200 million in additional annual costs resulting from more than 1.5 million hours of labor that pharmacists are projected to spend solely on submitting specific fields for pharmacy claims to third-party vendors to request rebates for 340B drugs.[22] But HRSA does not (and cannot) explain how it arrived at the premise that covered entities will readily be able to generate the pharmacy claims data and will spend only two hours per week on submissions. Manufacturers under the Rebate Program are requiring categories of data *never previously submitted to manufacturers*, including claims data from hospital-owned retail pharmacies and medical claims data, much of which is stored on different types of systems and would need to be migrated to platforms that are different from the ones that providers routinely use for the purpose of claims data submission. Indeed, the vast majority of hospital survey respondents reported that claims data submission under the Rebate Program would be highly or extremely burdensome, and almost all hospitals (99%) anticipate needing to allocate additional resources to manage the rebate

[21] 340B Webinar 12-4-2025, https://www.youtube.com/watch?v=Iw0kxqi74PE.

[22] Supporting Statement A, 340B Rebate Pilot Program Application, Implementation, and Evaluation, OMB Control No. 0906-0111-Extension, 90 Fed. Reg. 44197, 44198 (Sept. 12, 2025).

process, which includes preparing, submitting, and tracking data to request rebates and reconcile payments.[23] 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." Compl. ¶ 76 (quoting Comment ID HRSA-2025-0001-0052 at 13).

C. HHS Has Not Provided a Reasoned Explanation for Replacing 340B's Longstanding Upfront Discount Model with a Rebate Model.

HRSA's Rebate Program disturbs the way the 340B program has operated for more than 30 years as an upfront discount program (with the limited exception of the rebates it has blessed for ADAPs, *see supra* 4 n.3). This is significant because 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 under their group purchasing organization discounts or other commercial prices.

By allowing drug manufacturers to provide the 340B statutory drug discounts through rebates instead of upfront, the Rebate Program effectively requires cash-strapped covered entities to provide interest-free loans to drug manufacturers by purchasing 10 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 would 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 340B

[23] *Id.*

Providers have 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 operations" for safety-net providers, allowing them to "stretch scarce Federal resources as far as possible" so that they could reach more eligible patients.[24]

Although HRSA acknowledges in the Program notice that a rebate-based model would represent a fundamental change in how 340B has operated for more than three decades,[25] it has not provided a reasoned explanation for abandoning 340B's long-standing and successful operation as an upfront discount program. Indeed, HRSA itself has "long envisioned upfront discounts as the preferred price reduction mechanism, because '[c]overed entities generally preferred a discount system, because they could negotiate lower prices and needed less initial outlay of drug purchasing money.'"[26] As Plaintiffs have explained, such a seismic shift in the structure of 340B cannot lawfully proceed without a well-supported justification. HRSA has not identified one. Hospitals and patients will face immediate and irreparable harm due to a hasty restructuring of the 340B Program.

Instead, HRSA bases its justification on manufacturers' "inquiries" related to proposed rebate models for 340B, which HRSA says primarily pertain to 340B and Maximum Fair Price (MFP) deduplication and to "facilitate other aims such as the prevention of 340B Medicaid duplicate discounts and diversion."[27] As explained below, HHS can address MFP deduplication

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[24] *See* H.R. Rep. No. 102-384(II), at 12 (1992), 1992 WL 239341.

[25] 90 Fed. Reg. 38165 (Aug. 7, 2025).

[26] HHS Memorandum of Points and Authorities in Support of its Cross Motion for Summary Judgment and Opposition to Plaintiffs' Motions for Summary Judgment at 14, *Eli Lilly & Co. v. Kennedy,* No. 1:24-cv-03220-DLF (D.D.C. Mar. 17, 2025), ECF No. 35-1 (quoting 62 Fed. Reg. 45823, 45824 (Aug. 29, 1997)).

[27] 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program, 90 Fed. Reg. 36163 (Aug. 1, 2025).

without relying on rebates. And although several pharmaceutical companies have claimed in lawsuits against HHS that the 340B program suffers from rampant abuse pertaining to diversion and Medicaid duplicate discounts, HRSA's Rebate Program bars drug companies from denying rebates for those reasons, 90 Fed. Reg. at 38166, and the Rebate Program notice does not support those asserted concerns.

Moreover, the terms of use for Beacon Channel Management (Beacon), the technological platform selected by manufacturers to run the rebate program, confirm that the Rebate Program will be used to collect data wholly unrelated to the goals for the Program set forth in HRSA's notice.[28] For example, Beacon "enables analysis . . . of claims data for Manufacturers in order to identify . . . commercial payer, or other discounts that are ineligible for reimbursement by Manufacturers."[29] In other words, covered entities will be required to submit claims data to manufacturers so that manufacturers can police their commercial partners, which is entirely unrelated to the purposes of the 340B statute or to effectively managing the program. Rather than negotiating more favorable terms for its voluntary agreements with commercial partners, drugmakers shift the costs and heavy administrative burden of data sharing to safety-net providers.

Beacon's terms of use (to which covered entities must agree to access the platform) are also striking in their non-negotiable, one-sidedness. As one covered entity commenter explained, "[t]hese Terms are designed to benefit [the company that runs the platform and its parent company] and its manufacturer clients and shift effectively all risk associated with data sharing to covered entities." Compl. ¶ 93 (citing Comment ID HRSA-2025-0001-0974 at 11). Ultimately, these self-serving terms will allow manufacturers and their third-party vendor to monetize and benefit from

[28] Beacon Rebate Model Terms of Use, https://cm.beaconchannelmanagement.com/pages/terms (last visited Dec. 5, 2025).

[29] *Id.*

the collection of data wholly unrelated to the 340B statute or the Rebate Program. HHS plans to impermissibly delegate its authority under the 340B Program to Beacon, a private entity that is not even subject to the federal 340B statute or its enforcement mechanisms (leaving covered entities without recourse).

D. HHS Has Not Considered Less Costly Alternatives to the Program.

Further, a rebate model is not the only way to implement the Inflation Reduction Act (IRA)'s non-duplication provision, which bars covered entities from receiving discounts under both 340B and the IRA; there are other options. For example, manufacturers could work with 340B Providers on limited data sharing arrangements for 340B drugs that are dispensed to Medicare beneficiaries to ensure that providers will receive either the 340B discount or the MFP rebate, whichever is greater, as required by the IRA. This could be done either in advance of or after the MFP refund has been paid, potentially involving a neutral third party. This and other options have been presented to CMS by 340B Health, AEH, and AAMC.[30] In fact, CMS recently finalized a plan to collect this data beginning next year, but it is refusing to use it for purposes of implementing the IRA's non-duplication provisions.[31] As explained in 340B Health's comments to Centers for Medicare and Medicaid Services (CMS), there is simply no reason for HHS to mandate that covered entities submit data to manufacturers under the 340B Rebate Program when CMS can

[30] 340B Health Comment Letter to CMS relating to Medicare Drug Price Negotiation Program Draft Guidance (July 2, 2024), https://www.340bhealth.org/files/340B-Health-Comments-on-5.3.24-IRA-Draft-Guidance-7_.2.24.pdf; Joint Letter to CMS relating to Medicare Drug Price Negotiation Program Draft Guidance (July 2, 2024), https://essentialhospitals.org/wp-content/uploads/2024/07/Joint-Comments-on-5.3.24-IRA-Draft-Guidance-7.2.24.pdf.

[31] Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 49266 (Nov. 5, 2025), CMS-1832-F. CMS's stated purpose for collecting this data is to test the feasibility of collecting 340B claims data directly from covered entities to allow for the identification—rather than an estimation—of 340B Part D units. *Id.*

identify 340B claims and then share that information with manufacturers.[32] As a result, HHS will impose two separate and overlapping burdensome data production requirements on covered entities under two government programs, one requiring covered entities to submit data to manufacturers under the Rebate Program and another requiring they submit overlapping data to CMS so that it can identify 340B claims.

E. HHS Failed to Provide Adequate Notice to 340B Providers of the Rebate Program.

The immediate and irreparable harm to 340B Providers and their patients has been exacerbated during the Rebate Program implementation process as key programmatic information has been hidden throughout. HRSA has lacked transparency by refusing to publish manufacturers' plans, provided sparse guidance only through frequently asked questions, and changed requirements. For example, HRSA's initial Rebate Program notice did not specify all types of claims data that could be required by manufacturers. Only on October 30, 2025, did HRSA release the data that manufacturers can require for medical claims, giving 340B Providers just 60 days' notice before implementation of the requirements begin and no opportunity to comment on these fields.

Although HRSA's Rebate Program website lists the required data fields, it does not define them.[33] Shortly after HRSA announced approvals of manufacturers' Program proposals, the rebate platform rolled out descriptions of those fields on its website, including for medical claims data.[34] Those descriptions, however, are not universally defined or understood, creating significant confusion over the information that is required for those data fields. As a result, hospitals are

[32] 340B Health Comment Letter to CMS relating to Medicare Prescription Drug Inflation Rebate Program (Sept. 12, 2025), https://www.340bhealth.org/files/Final-340B-Health-Comments-CY-2026-PFS-Rule_9.12.25.pdf.

[33] HRSA, *340B Rebate Model Pilot Program*, https://www.hrsa.gov/opa/340b-model-pilot-program.

[34] Beacon Channel Management, *Rebate Model Frequently Asked Questions, Medical Claims Data*, https://support.beaconchannelmanagement.com/en/articles/9589827-rebate-model-frequently-asked-questions.

expending significant resources to identify the information that they are being asked to submit to request rebates, determining if they have that data easily available (many do not), and attempting expensive software changes to try to include the data required for rebate claims. This has effectively made HHS's already unreasonably short timeline for the Rebate Program even shorter and gives hospitals just a few weeks to evaluate whether their systems have the information required to request rebates or if changes to their operations would be needed (if even possible) to obtain the required data. None of this has been tested. Hospitals have hundreds of different accounts for the various entities it owns and operates whose billing systems could be significantly disrupted because of changes the hospital may need to make to have the required information to request rebates. The government is simply asking hospitals to do too much with too little information and giving them virtually no time.

CONCLUSION

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

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on December 11, 2025, I caused the foregoing to be served via the Court's ECF filing system on all registered counsel of record.

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