IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

KALDEROS, INC., *Plaintiff*, v. UNITED STATES OF AMERICA, *et al.*, *Defendants*.	No. 21-cv-2608 (DLF)

MOTION FOR LEAVE TO FILE FIRST AMENDED COMPLAINT

Plaintiff Kalderos, Inc. (Kalderos) respectfully moves the Court for leave to file the attached first amended complaint. *See* Fed. R. Civ. P. 15(d); *see also* Exhibit 1 (First Amended Complaint); Exhibit 2 (Redline Comparison of Original and Amended Complaints).

In 2021, Kalderos filed its original complaint to challenge actions by defendants that prevented manufacturers from adopting the Kalderos platform as a mechanism to implement their obligations under the 340B statute. *See* 42 U.S.C. § 256b. Since 2022, this case has been stayed pending resolution of appeals before the D.C. Circuit, which have now been resolved. Defendants have recently taken additional actions that further prevent manufacturers from adopting the Kalderos platform. To the extent necessary under Rule 15, Kalderos thus seeks leave to file this first amended complaint to address these most recent actions, which, along with the 2021 actions addressed in the original complaint, have caused and continue to cause concrete injury to Kalderos.

In support of this motion, Kalderos states as follows:

BACKGROUND

1. Kalderos filed this lawsuit in October 2021 to challenge actions taken by the Health Resources and Services Administration (HRSA), which prevented drug manufacturers from using Kalderos's electronic platform for administering the ceiling price under the 340B statute to covered

entities via a direct rebate from manufactures. Using Kalderos's platform would require covered entities to submit certain claims data to ensure that 340B pricing was appropriate. Under the Kalderos platform, manufacturers would condition covered entities' receipt of the 340B pricing rebate on the covered entities' use of Kalderos's platform.

2. In May 2021, HRSA took action to prohibit manufacturers from imposing any conditions on the receipt of 340B pricing. HRSA's actions prevented manufacturers from conditioning receipt of 340B pricing on the use of the Kalderos platform. Kalderos's original complaint challenged HRSA's actions as contrary to law (Count I) and arbitrary and capricious (Count II). *See* ECF No. 1 (Original Complaint) ¶¶ 82–97.

3. Before Kalderos's lawsuit could proceed further, the government requested, and this Court granted, a stay based upon the then-pending appeals in the D.C. Circuit in *Novartis Pharmaceuticals Corporation v. Johnson*, No. 21-5299, and *United Therapeutics Corporation v. Johnson*, No. 21-5304. On May 21, 2024, the D.C. Circuit resolved both appeals. *See Novartis Pharmaceuticals Corporation v. Johnson*, 102 F. 4th 452, 464 (D.C. Cir. 2024).

4. Following the D.C. Circuit's decision in *Novartis*, Kalderos and defendants (the parties) requested that the stay continue while the government decided whether to seek further review of the D.C. Circuit's decision. The government ultimately declined to seek rehearing en banc or further review in the Supreme Court.

5. On September 25, 2024, the parties submitted a joint status report requesting that the stay be continued an additional 30 days, so the parties could work out proposed next steps in this litigation. ECF No. 29. The parties then filed another joint status report on October 25, which requested an additional 30 days within which Kalderos could seek leave to file an amended complaint. ECF No. 30.

6. On October 28, the Court issued an order granting Kalderos permission to seek leave to file an amended complaint on or before November 24, 2024.

7. As discussed below, Kalderos seeks to file an amended complaint that also challenges actions that HRSA has taken while this case has been stayed that further prevent manufacturers from using the Kalderos platform. *See* First Amended Complaint ¶¶ 92–104.

LEGAL STANDARD

8. Rule 15(d) of the Federal Rules of Civil Procedure provides that "the court may, on just terms, permit a party to serve a supplemental pleading setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented." Fed. R. Civ. P. 15(d). A supplemental pleading is appropriate when a party seeks to put "forward new claims and defenses based on events that took place ***after*** the original complaint or answer was filed." *Hum. Genome Scis., Inc. v. Kappos*, 738 F. Supp. 2d 120, 122–23 (D.D.C. 2010) (emphasis added) (quoting *United States v. Hicks*, 283 F.3d 380, 386 (D.C. Cir. 2002)). The D.C. Circuit has held that a motion for leave to file a supplemental complaint should be "'freely granted when doing so will promote the economic and speedy disposition of the entire controversy between the parties, will not cause undue delay or trial inconvenience, and will not prejudice the rights of any of the other parties to the action.'" *Hall v. CIA*, 437 F.3d 94, 101 (D.C. Cir. 2006) (quoting 6A Wright & Miller, Federal Practice & Procedure § 1504, at 186–87 (2d ed. 1990)).

ARGUMENT

9. Kalderos's motion, to the extent necessary, should be granted because allowing Kalderos to file an amended complaint will "promote the economic and speedy disposition of the entire controversy between the parties." *Hall*, 437 F.3d at 101. Nor could it "delay" this proceeding or unfairly "prejudice" the government. *Id.*

10. *First*, the amended complaint will efficiently resolve the parties' entire controversy. The "controversy between the parties" here concerns HRSA's efforts to prevent manufacturers from imposing conditions on the receipt of 340B prices—efforts that have prevented manufacturers from adopting the Kalderos platform. Since early 2019, Kalderos has been communicating with HRSA to describe how its platform implements 340B pricing and prevents statutory violations that have plagued the 340B program for years. In submissions to HRSA in 2019 and 2020, Kalderos explained to HRSA that its platform used claims data to implement the statutory ceiling price through rebates provided to covered entities. Kalderos's original complaint challenged HRSA's 2021 actions that prohibited manufacturers from requiring use of Kalderos's platform as a condition of receiving 340B pricing. *See* Original Complaint ¶¶ 69–77.

11. As set out in the amended complaint, HRSA's recent actions are a continuation of the agency's efforts. Namely, over the last three months, HRSA has taken the position that manufacturers cannot use Kalderos's model because it administers 340B pricing via a rebate model. *See* First Amended Complaint ¶¶ 92–104. The amended complaint therefore supplements the original complaint by including two new claims challenging HRSA's actions. *See id.* ¶¶ 128–143. These claims, like Count I and Count II of the original complaint, allege that HRSA's recent actions are contrary to law (Count III) and arbitrary and capricious (Count IV). *See id.* These challenges to HRSA's most recent actions address how they have prevented manufacturers from adopting the Kalderos platform. Consequently, "[t]he interests of judicial economy and convenience would be served where, as here, [Kalderos's] motion to supplement [its] complaint raises similar legal issues to those already before the court, thereby averting a separate, redundant lawsuit." *Fund For Animals v. Hall*, 246 F.R.D. 53, 55 (D.D.C. 2007).

12. *Second*, granting leave to file the amended complaint will not delay the lawsuit or prejudice the government. Although the litigation is three years old, it is still in its procedural infancy. From early 2022 until now, the case was stayed (initially at the government's request). The government has yet to respond to Kalderos's original complaint. This is not a case where "[t]he parties have already completed multiple rounds of briefing on various dispositive motions." *Clean Water Action v. Pruitt*, 315 F. Supp. 3d 72, 84 (D.D.C. 2018). To the contrary, the government has filed no answer and no substantive motions have been filed.

13. Nor is this a case where the government would be prejudiced by the addition of new claims. Again, the government has yet to answer the initial complaint. And it would be far more costly—and an unnecessary drain on judicial resources—to separately litigate these inextricably connected claims, all of which concern the same, ongoing controversy surrounding the lawfulness of manufacturers' use of Kalderos's platform.

STATEMENT REQUIRED BY LOCAL RULE 7(m)

14. As required by Local Rule 7(m), Kalderos communicated with counsel for defendants with respect to the relief requested in this motion. On November 14, 2024, counsel for defendants informed Kalderos that "[t]he Government takes no position on Kalderos's motion at this time, but will apprise the Court of its position after reviewing Kalderos's motion and proposed complaint, within the time allotted under the FRCP and Local Rules."

CONCLUSION

For these reasons, to the extent that Rule 15(d) governs, Kalderos respectfully requests that the Court grant Kalderos's motion for leave to file an amended complaint.

DATED: November 14, 2024

Respectfully submitted,

/s/ Paul. J. Zidlicky

SIDLEY AUSTIN LLP
Paul J. Zidlicky (No. 450196)
pzidlicky@sidley.com
(Tele.) 202-736-8013
Elizabeth Hardcastle (pro hac vice forthcoming)
ehardcastle@sidley.com
(Tele.) 202-736-8697
1501 K Street, N.W.
Washington, DC 20005
(Tele.) 202-736-8000
(Fax) 202-736-8711

Trevor L. Wear (pro hac vice forthcoming)
twear@sidley.com
(Tele.) 312-853-7101
One South Dearborn
Chicago, IL 60603
(312) 853-7000
(312) 853-7036 (fax)

Counsel for Plaintiff Kalderos, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

KALDEROS, INC.,

Plaintiff,

v.

UNITED STATES OF AMERICA, *et al.*,

Defendants.

No. 21-cv-2608 (DLF)

PROPOSED ORDER

Upon consideration of Plaintiff's Motion for Leave to File First Amended Complaint, the Court hereby GRANTS Plaintiff's motion.

SO ORDERED.

Dated: _____

_____
The Honorable Dabney L. Friedrich
United States District Judge

Exhibit 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

KALDEROS, INC.
625 W. Adams Street, Suite 20-146
Chicago, IL 60661

Plaintiff,

v.

UNITED STATES OF AMERICA

CAROLE JOHNSON, Administrator of U.S. Health Resources and Services Administration
5600 Fishers Lane,
Rockville, MD 20852

U.S. HEALTH RESOURCES AND SERVICES ADMINISTRATION
5600 Fishers Lane,
Rockville, MD 20852

XAVIER BECERRA, Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, SW
Washington, DC 20201

Defendants.

Case No. 21-cv-2608 (DLF)

[PROPOSED] FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Kalderos, Inc., brings this suit against Defendants Carole Johnson, in her official capacity as Acting Administrator of the U.S. Health Resources and Services Administration; the U.S. Health Resources and Services Administration ("HRSA"); Xavier Becerra, in his official

capacity as Secretary of the U.S. Department of Health and Human Services; and the U.S. Department of Health and Human Services ("HHS") (collectively, "Defendants"), and alleges as follows:

INTRODUCTION

1. This case involves the intersection of two federal healthcare programs—the 340B Program, so called after Section 340B of the Public Health Services Act, 42 U.S.C. § 256b, and the Medicaid Drug Rebate Program. In Section 340B, Congress required drug manufacturers to sell outpatient drugs to "covered entities" at a reduced price as a condition for their drugs to be covered by Medicaid. In the Medicaid Drug Rebate Program, Congress required drug manufacturers to pay rebates to States on their Medicaid drug purchases as a condition of Medicaid coverage. Both programs are immense—in 2020, manufacturers paid approximately $44 billion in 340B discounts, in addition to the more than $35 billion they pay annually in Medicaid rebates. In 2022, manufacturers paid in excess of $52 billion in 340B discounts.

2. Recognizing that it would be unfair and unsustainable to require manufacturers to provide *both* a 340B price *and* a Medicaid rebate on the same unit for a drug dispensed to a patient of a 340B covered entity who is also a Medicaid beneficiary, Congress prohibited such "duplicate discounts." *See* 42 U.S.C. §§ 256b(a)(5)(A)(i), 1396r-8(j)(1). In addition, Congress prohibited covered entities from diverting, *i.e.*, reselling or otherwise transferring, 340B drugs to persons who are not patients of the covered entity. *See id.* § 256b(a)(5)(B).

3. Unfortunately, despite the statute's balanced design intended both to provide the 340B price to covered entities and to prevent duplicate discounts and diversion, the 340B program is fundamentally broken. In direct contravention of the statute, duplicate discounts and diversion of 340B drugs represent significant, ongoing problems for the 340B program. As documented in a series of recent reports by the Governmental Accountability Office ("GAO"), developments over

the last decade and weaknesses in federal oversight have caused these problems to grow unchecked, undermining the integrity of both programs. HRSA, the unit of HHS responsible for administering the 340B Program, has proven either unwilling or unable to address these concerns.

4. As a result, manufacturers are concerned that some covered entities are engaged in unchecked violations of the duplicate discount and diversion prohibitions. Multiple lawsuits were filed in multiple districts involving allegations by manufacturers that they are not obligated to make 340B prices available in connection with a covered entity's use of contract pharmacies, by which the manufacturers allege that the covered entities are responsible for both duplicate discounts and diversion.[1]

5. Covered entities and their representatives, for their part, have contended that manufacturers are not providing required 340B pricing. The 340B program thus faces a crisis of confidence, where neither manufacturers nor covered entities believe their counterparts are acting in the manner required by statute.

6. Plaintiff Kalderos, a technology company serving the healthcare industry, has developed an equitable, easy-to-use technology platform designed to ensure that 340B covered entities have confidence they are receiving the 340B prices to which they are entitled and that manufacturers have confidence they will not be subject to duplicate discounts and have some means to

[1] *See Sanofi-Aventis U.S., LLC v. HHS*, No. 3:21-cv-634-FLW (D.N.J. Jan. 12, 2021), *rev'd in part, affirmed in part*, *Sanofi Aventis U.S., LLC v. HHS*, 58 F.4th 696, 707 (3d Cir. 2023); *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-81-SEB-MJD (S.D. Ind. Jan. 12, 2021), *appeal docketed*, No. 21-3128 (7th Cir. 2021); *AstraZeneca Pharms. LP v. Becerra*, No. 1:21-cv-27 (D. Del. Jan. 12, 2021), *aff'd sub nom. Sanofi Aventis U.S., LLC v. HHS*, 58 F.4th 696, 707 (3d Cir. 2023); *Novo Nordisk, Inc. v. HHS*, No. 3:21-cv-806 (D.N.J. Jan. 15, 2021), *rev'd in part, aff'd in part*, *Sanofi Aventis U.S., LLC v. HHS*, 58 F.4th 696, 707 (3d Cir. 2023); *Novartis Pharms. Corp. v. Espinosa*, No. 1:21-01479-DLF (D.D.C. May 31, 2021), *aff'd* 102 F.4th 452 (D.C. Cir. 2024); *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-01686-DLF (D.D.C. June 23, 2021), *aff'd sub nom. Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. 2024).

address diversion concerns. In this regard, Kalderos seeks to be an honest broker and to assist both covered entities and manufacturers in being able to have their reasonable expectations met, with the goal of restoring both sides' confidence in the program. In short, Kalderos seeks to administer 340B transactions in an efficient, legally compliant manner to the benefit of all stakeholders.

7. Specifically, Kalderos developed its electronic platform as a mechanism to administer 340B pricing. Covered entities would use the Kalderos platform to share a minimum number of data elements on utilization where they wish to request the statutory ceiling price from manufacturers working with Kalderos. When requesting the 340B price, covered entities would provide Kalderos certain minimal claims information, including the drug's prescription or Rx number, the prescriber identification number, and other basic information. This information allows Kalderos to identify and prevent multiple discounts being provided on the same prescription and to prevent various forms of diversion in violation of the statute. Providing this information is not burdensome for covered entities. Prescription and prescriber identification is routinely secured in determining the appropriateness of pricing in managed care, pharmacy benefit manager, retail pharmacy, hospital, physician, and group purchasing organization contracts. This information also is commonly collected and maintained in an easily shareable format by covered entities or their third-party administrators to identify drug utilization that is potentially eligible for 340B pricing. Use of the Kalderos platform would be a condition required by manufacturers choosing to work with Kalderos for transactions under the 340B statute.

8. Under the Kalderos platform, covered entities would receive 340B pricing through a direct cash rebate from manufacturers. The platform's rebate process implements the 340B statute by ensuring that a manufacturer is not paid more than the ceiling price by the covered entity. Specifically, because the rebates under the Kalderos platform are provided directly to covered

entities in an efficient, timely, and transparent manner, there is no lawful basis for ignoring them when assessing whether the manufacturer was paid more than the ceiling price.

9. Kalderos has communicated with the Office of Pharmacy Affairs ("OPA") at HRSA and the Department over 20 times beginning in April 2019 to describe its solution and answer both OPA's and the Department's questions in detail. OPA and the Department assured Kalderos that they were considering Kalderos's model and would provide their analysis to Kalderos. Kalderos repeatedly stated to OPA and the Department that the manufacturers with which it expected to contract would need an assurance from Defendants that those manufacturers would be permitted, as a condition of making 340B pricing available, to require use of the Kalderos platform. Kalderos repeatedly stressed to Defendants that it was being prevented from launching and effectively marketing its solution because manufacturers had not been advised by Defendants that Kalderos's conditions of use were permissible. Kalderos was told that OPA had recommended in a memorandum to the Department that the Kalderos model be permitted.

10. In May 2021, however, HRSA abruptly announced an unqualified, absolute policy that no conditions—no matter how reasonable—could be imposed on the issuance of a 340B price. Under this policy, announced in a series of letters issued to manufacturers on May 17, 2021, manufacturers may not require covered entities to provide any claims information when requesting the statutory ceiling price, no matter how regularly it is supplied in verifying other, non-340B pricing throughout the healthcare industry. HRSA threatened manufacturers with enforcement action and civil monetary penalties if they did not immediately comply with HRSA's policy prohibiting the conditioning of 340B prices on the provision of claims data by covered entities.

11. In light of HRSA's blanket policy forbidding manufacturer conditions, Kalderos was largely unable to move forward with its model, with multiple manufacturers stating that they

would contract with Kalderos for services, but could not in light of Defendants' policy position. Accordingly, having unsuccessfully engaged with Defendants for more than 30 months, Kalderos brought this action under the Administrative Procedure Act ("APA") to challenge the unlawful and arbitrary and capricious policy articulated in the May 17, 2021 letters.

12. On January 28, 2022, this Court granted a stay in this case pending the D.C. Circuit's decision in *Novartis Pharmaceuticals Corp. v. Espinosa*, No. 21-5299, and *United Therapeutics Corp. v. Espinosa*, No. 21-5304. *See* Order [D.E. 26] at 1 (Jan. 28, 2002). In doing so, this Court observed that (1) "the D.C. Circuit's ruling in *Novartis* will not answer all questions present in this case," *id.* at 2, but (2) it "could impact the resolution of Kalderos's claims," *id.* at 3. Both observations proved correct.

13. On May 21, 2024, the D.C. Circuit rejected HRSA's position that "section 340B prohibits drug manufacturers from imposing any conditions on the distribution of discounted drugs to covered entities." *Novartis v. Johnson,* 102 F.4th 452, 459 (D.D.C. 2024). With respect to the specific conditions identified by the manufacturers—including a claims data requirement—the D.C. Circuit held, based upon the record before the court, that the conditions "do not violate section 340B on their face." *Id.* at 463–64.

14. Relying on the D.C. Circuit's decision in *Novartis*, Kalderos undertook further steps to ensure that manufacturers could adopt its platform. On August 7, 2024, Kalderos entered into an agreement with Eli Lilly & Company ("Lilly") through which Lilly would use the Kalderos platform to satisfy its obligations under the 340B statute.

15. In August and September 2024, Lilly and Kalderos communicated with HRSA concerning the Kalderos platform. They explained that the Kalderos platform (i) requires the submission of claims data from covered entities (to provide transparency and prevent duplicate discounts

and diversion) and (ii) provides covered entities a direct cash rebate to ensure that they receive 340B pricing. Under the Kalderos platform, covered entities would receive a direct rebate from the manufacturer on eligible 340B drug purchases within seven days of submitting the necessary claims data.

16. On September 18, 2024, HRSA sent Lilly a letter stating that adoption of the Kalderos platform "would be inconsistent with the statutory requirements for the 340B Program, which require the approval of a rebate model such as Lilly has proposed." Letter from HRSA to Eli Lilly at 1 (Sept. 18, 2024) ("September 18 Decision").

17. Around the same time, HRSA rejected another manufacturer's proposal to provide the 340B ceiling price through a rebate, threatening that doing so would subject the manufacturer to cancelation of its Pharmaceutical Pricing Agreement ("PPA") and civil monetary penalties.

18. HRSA's rejection of the Kalderos platform is contrary to law and arbitrary and capricious. *First*, insofar as HRSA rejected the Kalderos platform because it requires claims data, the agency's action was contrary to law. As *Novartis* recognized, section 340B does not prohibit manufactures from requiring covered entities to provide basic claims information, including the Rx number and prescriber identification number, as a condition of their offers to sell 340B drugs at the statutory ceiling price.

19. To the contrary, collection of basic claims data is necessary to the proper operation of the 340B statute by allowing manufacturers and covered entities to identify and avoid duplicate discounts and diversion and to implement properly the 340B statute's Administrative Dispute Resolution ("ADR") process. 42 U.S.C. § 256b(d)(3).

20. HRSA's claims-data based objection is also arbitrary and capricious. HRSA previously issued guidance in 1994 that allowed manufacturers to "request standard information" from

covered entities as a delivery condition. HRSA has arbitrarily departed from that policy without a reasoned explanation and without grappling with the crucial role that claims-data requirements serve in preventing duplicate discounts and diversion.

21. *Second*, HRSA's rejection of the Kalderos platform because it allows for direct rebates violates the 340B statute and is arbitrary and capricious. The 340B statute expressly authorizes drug manufacturers to offer the 340B ceiling price through rebates or discounts to covered entities. 42 U.S.C. § 256b(a)(1). Nothing in the statute gives HRSA authority to demand preapproval of a manufacturer's provision of the ceiling price, whether that be through a rebate or a discount.

22. As with HRSA's opposition to claims-data requirements, HRSA's policy rejecting rebates also is arbitrary and capricious. HRSA has widely permitted, without prior authorization, rebates in the form of product replenishment for a number of years and has described that model in court filings. HRSA also has previously recognized that manufacturers may take into account rebates in offering the statutory ceiling price under the 340B program. *See* 1998 Guidance, 63 Fed. Reg. 35,239, 35,242 (June 29, 1998). HRSA has failed to provide a reasoned explanation for its policy or its rejection of the Kalderos platform.

23. In line with the D.C. Circuit's decision in *Novartis*, the Court should now make clear that manufacturers may require covered entities seeking the 340B ceiling price to provide the basic claims information needed (1) to prevent duplicate discounts and diversion, (2) to restore the confidence that covered entities are, in fact, receiving the prices to which they are entitled, and (3) to ensure the integrity of the 340B program as envisioned by Congress.

24. The Court also should reject the agency's determination that rebates violate the 340B statute because they require covered entities to pay more than the statutory ceiling price.

That position is contrary to the statute. Indeed, Defendants have permitted rebates as a method to provide the statutory ceiling price under the 340B statute. Defendants cannot and should not prohibit the Kalderos platform, which ensures that the 340B discount price is offered to covered entities through a direct cash rebate and that manufacturers are not required to provide duplicate discounts or discounts in cases of drug diversion in violation of the 340B statute.

PARTIES

25. Plaintiff Kalderos, Inc. is a technology company focused on solving the problems facing the United States healthcare system. Kalderos is a Delaware corporation with its principal place of business at 625 West Adams Street, Suite 20-146, Chicago, IL 60661.

26. Carole Johnson is the Administrator of HRSA.[2] In that capacity, she has ultimate responsibility for activities at HRSA, including the actions complained of herein. She is being sued in her official capacity only.

27. HRSA is an agency of the United States and a division of HHS. Its headquarters and principal place of business are at 5600 Fishers Lane, Rockville, MD 20852.

28. Xavier Becerra is the Secretary of HHS. In this capacity, he has ultimate responsibility for activities at HHS, including the actions complained of herein. He is being sued in his official capacity only.

29. HHS is a department of the United States. HHS oversees the activities of HRSA. HHS's headquarters and principal place of business are at 200 Independence Avenue SW, Washington, DC 20201.

[2] "[T]he United States may be named as a defendant in any [APA] action, and a judgment or decree may be entered against the United States: *Provided*, That any mandatory or injunctive decree shall specify the Federal officer or officers (by name or by title), and their successors in office, personally responsible for compliance." 5 U.S.C. § 702.

JURISDICTION AND VENUE

30. Kalderos brings this action pursuant to the APA, 5 U.S.C. §§ 701–706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202.

31. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1361.

32. The Court has authority to grant the relief requested by Kalderos pursuant to the APA, 5 U.S.C. §§ 701–706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202.

33. Venue is proper in this District pursuant to 28 U.S.C. § 1391(e)(1) because at least one Defendant is an officer or agency of the United States and resides in this District.

GENERAL ALLEGATIONS

A. The 340B Program

34. Congress established the 340B Program in 1992. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585 § 602(a), 106 Stat. 4943, 4967 (adding Section 340B to the Public Health Service Act, codified at 42 U.S.C. § 256b); *see* H.R. Rep. No. 102-384 (II), at 11–13 (1992).

35. "The 340B Program is tied to the earlier-enacted, much larger Medicaid Drug Rebate Program." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 114 (2011). Medicaid is a cooperative federal-state program through which the federal government provides financial assistance to States so that they may furnish medical care to needy individuals. *See* 42 U.S.C. § 1396 *et seq.* Enacted in 1990, the Medicaid Drug Rebate Program allows drug manufacturers to obtain coverage for their drugs under Medicare Part B and Medicaid if they enter into an agreement with HHS to provide rebates to States that are generally intended to give States the "'best' prices" on their Medicaid drug purchases. *See Astra*, 563 U.S. at 114–15 (citing 42 U.S.C. § 1396r-8(a)).

36. After enactment of the Medicaid Drug Rebate Program, manufacturers could no longer provide voluntary discounts to safety net hospitals and clinics that had pharmacies and

dispensed outpatient drugs to their patients, without affecting their Medicaid rebate payments. As a result, manufacturers stopped providing the discounts that they had previously offered. Congress established the 340B Program to ensure that these entities, now called "covered entities," could have discounted medications restored, carving out the discounts manufacturers offered to covered entities from the Medicaid "best price" calculation. *See* 42 U.S.C. §§ 256b, 1396r-8(c)(1)(C)(i); *see also* H.R. Rep. No. 102-384 (II), at 11–12 ("The Committee expects that this exemption will remove any disincentive that the Medicaid rebate program creates to discourage manufacturers from providing substantial voluntary or negotiated discounts to these clinics, programs, and hospitals.").

37. The 340B Program requires drug manufacturers to sell certain outpatient drugs to covered entities at reduced prices; in return, manufacturers can have their drugs covered by Medicaid. *See Astra*, 563 U.S. at 113, 115–16; 42 U.S.C. § 1396r-8(a)(1), (5). Section 340B directs the Secretary of HHS to enter into agreements with drug manufacturers under which the amount required to be paid by covered entities for "covered outpatient drugs" must not exceed a "ceiling price" calculated pursuant to a formula set forth in the statute. *See* 42 U.S.C. § 256b(a)(1)–(2). Paragraph (a)(1) provides that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2)." *Id.* "Covered outpatient drugs" are defined by reference to the drugs subject to the Medicaid Drug Rebate Program. *See id.* §§ 256b(b), 1396r-8(k)(2).

38. By statute, the agreement between the drug manufacturer and HHS, referred to as a Pharmaceutical Pricing Agreement ("PPA"), must "require 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." The PPAs "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them." *Astra*, 563 U.S. at 118. "The statutory and contractual obligations … are one and the same." *Id.*

39. Section 340B also imposes certain obligations on covered entities participating in the program. To qualify as a "covered entity," the entity must be one of the fifteen types of entities enumerated in Section 340B(a)(4), such as "critical access" hospitals serving rural communities, "disproportionate share" hospitals serving a disproportionate number of low-income patients, and certain community health centers. *See* 42 U.S.C. § 256b(a)(4). In addition, the covered entity must "mee[t] the requirements described in paragraph (5)." *Id.*

40. Paragraph (5) prohibits covered entities from (1) requesting payment under Medicaid for drugs subject to an agreement under Section 340B if the drug is also subject to the payment of a rebate under Medicaid (the "duplicate discount" prohibition), *id.* § 256b(a)(5)(A)(i), and (2) reselling or otherwise transferring a drug subject to an agreement under Section 340B to a person who is not a patient of the covered entity (the "diversion" prohibition), *id.* § 256b(a)(5)(B).

41. Although covered entities are subject to audits by HRSA and manufacturers for compliance with the prohibitions on duplicate discounts and diversion, *id.* § 256b(a)(5)(C), these retrospective remedies have proven quite clearly deficient and almost entirely ineffective at preventing violations, and nothing in the statute precludes the adoption of prophylactic measures to prevent duplicate discounts and diversion.

B. HRSA's Guidance on Manufacturer Conditions

42. Section 340B specifies only that manufacturers must offer to sell covered drugs at the ceiling price specified in the statute if other customers are offered such drugs. The statute otherwise does not restrict the terms and conditions for 340B sales, which manufacturers and 340B covered entities may determine for themselves through negotiation.

43. In 1994, HRSA issued guidance addressing conditions that manufacturers may place on their offers to sell 340B drugs to covered entities at the ceiling price. Without citing statutory authority or a statutory basis, the guidance provides that "[a] manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions." 59 Fed. Reg. 25,110, 25,113 (May 13, 1994) ("1994 Guidance"). The 1994 Guidance enumerates five categories of "assurances" that "may not be required": "(1) eligibility to participate in the program; (2) utilization of covered outpatient drugs only in authorized services; (3) maintaining the confidentiality of the drug pricing information; (4) permitting the manufacturers to audit purchase, inventory, and related records prior to the publication of approved . . . guidelines; and (5) submitting information related to drug acquisition, purchase, and inventory systems." *Id.* at 25,113–14. The agency further stated that "[m]anufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective," or "place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program." *Id.* at 25,113.

44. Although HRSA failed to establish how the 1994 Guidance was itself authorized by the statute, the 1994 Guidance did not, in any event, purport to prohibit all manufacturer conditions. To the contrary, it provided that manufacturers were permitted to "include provisions that address customary business practice, request standard information, or include other appropriate

contract provisions." *Id*. at 25,114. The 1994 Guidance also explained that "[i]f a manufacturer asks a covered entity whether the entity is in fact participating in the Section 340B discount program, the entity must supply the manufacturer with this information." *Id.*

45. In addition, HRSA has long acknowledged that manufacturers can impose certain conditions on 340B sales. For instance, HRSA permits manufacturers to impose a condition that, to secure a 340B price, a covered entity must enroll with an intermediary, called a wholesaler, and seek reduced 340B prices only through that mechanism. Enrollment with a wholesaler requires covered entities to meet certain conditions. These conditions may include a credit check, minimum purchasing obligations, account set-up forms, copies of balance sheets, income statements, tax information, vendor statements, a voided check, copies of licenses, a contract with wet signature, and a security interest in covered entity personal property. All of these conditions are more demanding than those that would be required to collaborate with Kalderos. Further, many of the conditions wholesalers impose are the same as those sought by Kalderos, including the use of a web-based ordering and financial system with unique user ID and password.

46. As another example, HRSA has long acknowledged that manufacturers can impose a condition that covered entities must purchase through a limited set of distribution points, or even a single distribution point, when limited supply of a product is available, in order to control a shortage risk or to prevent covered entities from attempting to capitalize inappropriately on the "spread" between a very low 340B price and a much higher reimbursement from a third-party payor. *See* HRSA, Clarification of Non-Discrimination Policy (May 23, 2012) (policy on "manufacturer limitations or conditions on sales of covered outpatient drugs to eligible 340B entities," stating that "manufacturers have the ability to develop alternate allocation procedures during situations when the available supply of a covered drug is not adequate to meet market demands").

47. The HRSA website contains multiple notices by manufacturers issued over a number of years that HRSA has reviewed and that impose limited distribution systems. *See* HRSA, *Manufacturer Notices to Covered Entities*, https://www.hrsa.gov/opa/manufacturer-notices/index.html (last visited Oct. 15, 2024) (including limited distribution network conditions from 9 manufactures in 2021 alone and limited distribution network conditions imposed by over 25 manufacturers in 2020). HRSA not only has not forbidden such conditions, but has facilitated manufacturer communication of these conditions and refused to support some covered entities in their opposition to these programs, stating that these conditions are consistent with the statute.

48. Although HRSA has requested advance notice of these conditions, it has not stated that manufacturers are required to provide such notice, or to obtain HRSA approval, before imposing such conditions. *See* HRSA, *Clarification of Non-Discrimination Policy* (May 23, 2012) (stating that "[a]lthough prior notification by manufacturers is not currently required, HRSA believes that voluntarily providing OPA with timely notification will benefit manufacturers as well as covered entities by reducing the chance for misunderstandings about the requirements of the 340B Program and lessen the potential for disputes").

C. The Problem of Duplicate Discounts and Diversion

49. Duplicate discounts and diversion are significant challenges to the integrity of the 340 Program, and manufacturers have a legitimate interest in addressing these issues through reasonable conditions designed to ensure compliance with statutory requirements.

50. A duplicate discount occurs when a manufacturer sells a covered drug to a covered entity at the 340B ceiling price and then also is invoiced for a Medicaid rebate on the same unit. Because the 340B price reduction and the Medicaid rebate can *each* be as much as 50 percent of a drug's cost, or even more, manufacturers subjected to duplicate discounts incur significant

financial losses. A duplicate discount also may occur when the same covered entity seeks a second discount on the same 340B covered drug purchase, or multiple different covered entities each request 340B discounts on the same covered drug purchase. In addition, as a result of the Inflation Reduction Act, there is a risk of duplicate discounts between the 340B price and the Maximum Fair Price ("MFP"), or even triplicate discounts among 340B, MFP, and Medicaid rebates when the patient of a covered entity is eligible for both Medicare and Medicaid. This in turn contributes to the cost of prescription drugs for everyone, as duplicate or triplicate discounts, once provided, can only rarely be secured back by the manufacturers.

51. Diversion occurs when a covered entity resells or transfers a drug subject to a 340B agreement to a person who is not a patient of the covered entity. This may happen, for example, when 340B drugs are given to individuals who are not receiving healthcare services from the covered entity or are receiving services that are not consistent with the type of services for which the covered entity qualified for 340B status. Certain covered entities also are not permitted to purchase 340B drugs through group purchasing organizations, which secure their own discounts from manufacturers. *See* 42 U.S.C. § 256b(a)(4)(L)(iii). Diversion harms manufacturers by requiring them to provide price reductions on transactions that fall outside the 340B program, again increasing the cost of prescription drugs for everyone.

52. Recognizing these problems, Congress prohibited covered entities from subjecting manufacturers to duplicate discounts by requesting payment under Medicaid for 340B drugs that also are subject to a rebate under the Medicaid Drug Rebate Program. *See id.* § 256b(a)(5)(A)(i). Congress similarly prohibited covered entities from diverting 340B drugs. *See id.* § 256b(a)(5)(B).

53. Congress further directed the Secretary to "establish a mechanism to ensure that covered entities comply with" the prohibition on duplicate discounts, *id.* § 256b(a)(5)(A)(ii), and

to "provide for improvements in compliance by covered entities with the requirements of [Section 340B] in order to prevent diversion and violations of the duplicate discount provision," *id.* § 256b(d)(2)(A), including by developing "detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts," *id.* § 256b(d)(2)(B)(iii).

54. Despite Congress's expressed concern about duplicate discounts and diversion and the threat they pose to the integrity of the 340B Program, HRSA has failed to live up to its statutory obligations, and duplicate discounts and diversion remain significant problems for the 340B program. The Government Accountability Office ("GAO"), for instance, has issued multiple reports detailing serious shortcomings in HRSA's efforts to prevent violations. *See* GAO, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (June 2018) ("2018 GAO Report"); GAO, *340B Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* (Jan. 2020) ("January 2020 GAO Report"); GAO, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements* (Dec. 2020) ("December 2020 GAO Report").

55. In its most comprehensive report on the subject of duplicate discounts, GAO concluded that "HHS does not have reasonable assurance that states and covered entities are complying with the prohibition on duplicate discounts," January 2020 GAO Report, leaving "drug manufacturers at risk of providing duplicate discounts" and "compromis[ing] the integrity of the 340B Program." *Id.* at 27.[3]

[3] These conclusions echo similar findings regarding duplicate discounts reflected in other government reports and testimony. *See also* GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 at 31, tbl. 2 (Sept. 2011) (recommending that HRSA "[d]evelop more detailed guidance on the procedures covered entities can

56. GAO explained that "[i]n recent years, the potential for duplicate discounts has increased due to substantial growth in the 340B Program and the expansion of the Medicaid Drug Rebate Program" in 2010 to include drugs provided under Medicaid managed care in addition to drugs provided under Medicaid fee-for-service. *Id.* at 2–3.[4] "Specifically, from 2010 to 2019, the number of covered entities participating in the 340B program increased from nearly 9,700 to nearly 13,000." *Id.* at 2. And the number of "contract pharmacies" dispensing 340B drugs "increased from about 1,300 at the beginning of 2010 to around 23,000 in 2019." *Id.*[5] As a result of these developments, "total Medicaid drug rebates more than doubled from about $15 billion in fiscal year 2011 to more than $36 billion in fiscal year 2018." *Id.* at 3.

---

follow to avoid the Medicaid duplicate discount"); OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 2 (Feb. 4, 2014) (finding that "most covered entities in [the] study do not conduct all of the oversight activities recommended by HRSA" to prevent duplicate discounts); House Energy & Commerce Committee, *Review of the 340B Drug Pricing Program* at 37 (Jan. 10, 2018) (explaining that "duplicate discounts" are a "growing problem" whose "volume" "may be far greater than has been previously realized" and that "some covered entities fail to adequately protect against the risk of duplicate discounts"); OIG, *Testimony before the United States Senate on Health, Education, Labor, and Pensions* at 3–4, 5 (May 15, 2018) (explaining that lack of transparency hampers 340B payment accuracy and that "methods that operate at the claim level can improve accuracy in identifying 340B claims and thereby help prevent duplicate discounts and improve collection of rebates").

[4] States provide Medicaid services through either fee-for-service or managed care. Under fee-for-service, States reimburse providers directly for each service delivered. Under managed care, States typically contract with managed care plans to provide a specific set of services to Medicaid beneficiaries (which could include drugs) and prospectively pays each plan a set amount per beneficiary per month to provide or arrange those services. The Medicaid Drug Rebate Program had historically been limited to drugs provided under fee-for-service, but in 2010, the Patient Protection and Affordable Care Act expanded the Program by also requiring drug manufacturers to provide rebates for drugs provided under managed care. *See* Pub. L. No. 111-148, § 2501(c), 124 Stat. 119, 308 (2010) (codified at 42 U.S.C. §§ 1396b(m)(2)(A)(xiii), 1396r-8(b)(1)).

[5] Covered entities contract with pharmacies to dispense 340B drugs to the covered entities' patients. Before 2010, HRSA permitted covered entities to designate only one contract pharmacy for dispensing 340B drugs. In 2010, HRSA changed that policy and permitted covered entities to contract with an unlimited number of pharmacies, but failed to impose meaningful limitations or safeguards. *See* 75 Fed. Reg. 10,272 (Mar. 5, 2010).

57. GAO found "several areas of weakness in HRSA's oversight processes that impede its ability to ensure that duplicate discounts are prevented or remedied." *Id.* at 23. For example, "HRSA does not assess whether covered entities are actually following state policies and procedures regarding the use and identification of 340B drugs for Medicaid beneficiaries," which is "inconsistent with federal standards for internal control." *Id.* at 24. Consequently, "HRSA's audits do not provide the agency with reasonable assurance that covered entities are taking the necessary steps to prevent duplicate discounts," and "manufacturers are at risk of being required to erroneously provide duplicate discounts for Medicaid drugs." *Id.* at 25.

58. In addition, "HRSA audits do not assess for the potential for duplicate discounts in Medicaid managed care," *id.*—even though "the majority of Medicaid enrollees, prescriptions, and spending for drugs are in managed care, and the drug manufacturers [GAO] contacted believe that duplicate discounts are more prevalent in Medicaid managed care than [fee-for-service]." *Id.* at 26; *see also id.* at 6 & n.14 (noting that in fiscal year 2018, "71 percent of Medicaid drug prescriptions were in managed care"). Ten years after Congress expanded the Medicaid Drug Rebate Program to include managed care, "HRSA still has not issued guidance on how covered entities should prevent duplicate discounts in Medicaid managed care and has indicated that it is not pursuing new guidance at this time." *Id.* at 30.[6] This inaction, GAO observed, "is contrary to federal law," *id.* at

[6] In 1993, to comply with the statutory mandate to "establish a mechanism to ensure that covered entities comply" with the prohibition on duplicate discounts, 42 U.S.C. § 256b(a)(5)(A)(ii), HRSA required covered entities that provide 340B drugs to Medicaid patients to provide the agency with the provider numbers they use to bill the State for those drugs. *See* 58 Fed. Reg. 27,293 (May 7, 1993). That information should be included in a "Medicaid Exclusion File," which States can use to identify 340B drugs. *See* January 2020 GAO Report at 11. But this file does not capture covered entities' provision of 340B drugs in the Medicaid managed care context, and HRSA still "has not created a mechanism for covered entities to use to identify 340B drugs provided to Medicaid managed care beneficiaries." *Id*. While HRSA has "recognize[d] the need to address covered entities' role in preventing duplicate discounts under Medicaid managed care," HRSA, Rel. No. 2014-1,

26, and "continues to leave the 340B Program vulnerable" to duplicate discounts, *id.* at 30; *see also* 2018 GAO Report at 40 ("Until HRSA develops guidance and includes an assessment of the potential for duplicate discounts in Medicaid managed care as part of its audits, the agency does not have assurance that covered entities' efforts are effectively preventing noncompliance.").

59. "[M]anufacturers lack complete information on the extent to which covered entities use 340B drugs for Medicaid beneficiaries" because HRSA does not collect "information on whether covered entities are using 340B drugs for Medicaid managed care beneficiaries," and the data it does collect may not include "information on contract pharmacies that are dispensing these drugs to Medicaid beneficiaries on covered entities' behalf." January 2020 GAO Report at 32.

60. Moreover, although "drug manufacturers can request approval from HRSA to audit a covered entity to investigate suspicions of duplicate discounts," the manufacturers must first "document reasonable cause." *Id.* at 34. And because "HRSA requires the drug manufacturer to use an independent auditor who follows government auditing standards," the "cost of audits may outweigh the benefits received in the form of repayments." *Id.* Manufacturers that have pursued audits have found the process to be burdensome and ineffective, with HRSA failing to intervene and require covered entities to return improper discounts. Indeed, in the managed care context, "HRSA does not require covered entities to repay manufacturers for duplicate discounts." *Id.*

61. The result is a broken system in which HRSA has been either unwilling or unable effectively to ensure compliance with statutory requirements and prevent duplicate discounts.

Clarification on Use of the Medicaid Exclusion File at 3 (Dec. 12, 2014), it has cited its own lack of guidance as the basis for "not requiring covered entities to address identified duplicate discounts related to Medicaid managed care." January 2020 GAO Report at 26.

62. Even with its readily apparent failings, HRSA's program audits for fiscal years 2012–2019, as reported by GAO, found more than 400 duplicate discount violations. *See* December 2020 GAO Report at 14. Kalderos's own analysis confirms the extensive nature of the problem. Kalderos confirmed duplicate discounts exceeding $23 million in 2019, up from the $17 million it documented in 2017. Based on its extrapolation of these findings, Kalderos estimates that in 2019 manufacturers, as a whole, paid a total of more than $1.2 *billion* in duplicate discounts.

63. Diversion, too, is a significant concern. HRSA's audits indicate that the problem is extensive. HRSA's 1,240 audits for fiscal years 2012–2019 documented more than 450 instances of diversion, plus an additional 83 findings related to inadequacies in covered entities' efforts to prevent diversion. *See* December 2020 GAO Report at 14. As with duplicate discounts, the diversion issue has been exacerbated by the rise in the use of contract pharmacies to dispense 340B drugs on covered entities' behalf. *See* 2018 GAO Report at 44 (reporting that 66 percent of the diversion findings in HRSA's audits "involved drugs distributed at contract pharmacies"); GAO, *Drug Discount Program: Status of GAO Recommendations to Improve 340B Drug Pricing Program Oversight* at 9 (Mar. 2015) (explaining that "increased use of the 340B Program by contract pharmacies and hospitals may have resulted in a greater risk of drug diversion to ineligible patients, in part because these facilities were more likely to serve patients that did not meet the definition of a patient of the program").[7]

64. 340B covered entities also have their concerns. Some have expressed the view that they are not always receiving the statutory ceiling price for covered outpatient drugs.

[7] As indicated previously, Kalderos takes no position as to whether contract pharmacy transactions are contrary to the 340B statute. That issue is being litigated elsewhere by other parties. *See supra*, n.1.

65. Some covered entities have also stated their belief that (1) States have not acted on information that covered entities have supplied to them and (2) despite access to data indicating that a 340B price has already been claimed on that utilization, States have claimed a duplicate Medicaid rebate. Covered entities complain that this creates the risk that they will be forced to return a 340B price that they have previously received, or at the very least, will be embroiled in a long, burdensome duplicate discount dispute.

66. Some covered entities have expressed frustration that HRSA has failed to develop and implement a specific means to identify 340B utilization that relates to a Medicaid managed care beneficiary. Covered entities have stated that they have been unnecessarily involved in duplicate discount disputes that are a function of inadequate Medicaid systems.

D. Kalderos's Solution

67. Kalderos understands the immense complexities and issues plaguing the 340B program. Kalderos is not on any stakeholders' "side," but rather is committed to being an evenhanded broker administering a fair and efficient process that helps all stakeholders participate in this important program. Accordingly, Kalderos has invested significantly in technology designed to work with the 340B systems and the processes of covered entities.

68. In 2016, Kalderos concluded that a principal problem causing the breakdown in the 340B Program, from both a covered entity and a manufacturer perspective, was a failure to communicate essential information among covered entities, state Medicaid agencies, and manufacturers. Kalderos designed solutions to address this information gap and to facilitate efficient and compliant drug transactions effectuating the 340B ceiling price.

69. In particular, Kalderos created a multi-sided platform, *i.e.*, a platform that connects two or more interdependent user groups. The system is capable of multiple configurations. These

systems are well known and widely used in other contexts. For example, two commonly recognized multi-sided platforms are the Uber and Lyft applications, which, at any given moment in any given city, connect hundreds or thousands of willing drivers to as many potential passengers. These applications close the information gap between drivers and passengers and assist them in arranging and completing the transaction. Kalderos's solution similarly is designed to connect 340B providers to manufacturers selling drugs through the 340B program to efficiently facilitate 340B transactions in a compliant manner, ensuring that both sides can have confidence in the transactions.

70. Kalderos's solution works as follows. A manufacturer involved with the 340B Program contracts with Kalderos to facilitate 340B transactions. The manufacturer then informs covered entities that they will need to use the Kalderos platform to obtain 340B prices from that manufacturer.

71. Covered entities (or their 340B third-party administrators or vendors) review and accept Kalderos's terms and conditions for service to utilize the platform in connection with purchases of drug manufacturers' drugs under the 340B Program. The terms and conditions are intended to be similar to—or even easier to meet than—those that apply under traditional enrollment with a wholesaler by a covered entity, where the wholesaler submits 340B discount chargebacks to a manufacturer on behalf of a 340B covered entity.

72. Among these terms and conditions is a requirement that covered entities (or their 340B third-party administrators or vendors), when submitting a request for 340B prices, provide certain minimal claims information. That claims information includes the Rx number, prescriber identification number, national drug code, number of units, date of service, and 340B covered entity identification number. This small set of data points is sufficient to enable Kalderos to address duplicate discounts and diversion issues.

73. Information like this is routinely required by manufacturers that offer price concessions to a broad range of non-340B customers, including managed care companies, hospitals, physician practices, retail pharmacies, group purchasing organizations, and even States participating in the Medicaid program. *See e.g.*, MDRP Electronic State Invoice Form CMS-R-144, Data Definitions (effective July 1, 2021), https://www.medicaid.gov/medicaid/prescription-drugs/downloads/cms-r-144-state-invoice-data-definitions-jul-2021.pdf (addressing the regular practice of state Medicaid programs to request rebates by providing record ID, labeler code, units reimbursed, package size, number of prescriptions, and other data in their pricing invoices to manufacturers); HHS Office for Civil Rights, HIPAA FAQ 455, https://www.hhs.gov/guidance/document/faq-455-does-privacy-rule-permit-health-plans-disclose-protected-health-information (addressing "health plans disclos[ing] protected health information, such as prescription numbers, to a pharmaceutical manufacturer" for purposes of "adjudicating claims submitted under a drug rebate contract"); Mark Campbell, RxBenefits, *What Employers Need to Know about Drug Rebates* (June 24, 2021), https://www.rxbenefits.com/blogs/understanding-the-role-of-drug-rebates/ (drug price concessions "are paid on a per claim basis"); National Council for Prescription Drug Plans, Manufacturer Rebate Flat File Implementation Guide, Version 07 (Jan. 24, 2018), at 15, 20–22 (standard setting organization "flat file" used by "State Medicaid Agencies, Health Maintenance Organizations . . . , Pharmacy Benefit Managers . . . , Long Term Care Facilities, Mail Order Providers, Insurance Carriers, Employer Groups, etc." to seek drug price concessions includes such standard data elements as "Claim Number", "Prescriber ID", "Prescription/Service Reference Number"); *see also* 63 Fed. Reg. at 35,241 (HRSA itself encouraging state AIDS Drug Assistance Programs to make "detailed and accurate" "claim data" available to manufacturers).

74. After the parties are set up on the Kalderos platform, the covered entity (and/or its third-party administrator or vendor) assesses the transaction. If it believes it is appropriate to submit the transaction for 340B pricing, it supplies the claim information to Kalderos. Kalderos uses the prescription information provided by the covered entity to determine if a Medicaid rebate already has been provided for the drug being dispensed, which would be unlikely given the lagged timing of Medicaid rebate invoices. If no duplicate discount is present at the time the covered entity submits the 340B price request, Kalderos informs the manufacturer, which then reviews Kalderos's recommendation and agrees to provide 340B pricing. Kalderos then notifies the covered entity that the transaction qualifies for 340B pricing and provides instructions to the manufacturer's bank to remit payment through a direct cash rebate to the covered entity within days of the covered entity's request. This is all done electronically and the covered entity has real-time, around-the-clock visibility into the transaction's status. If a Medicaid rebate, a price or a rebate under the IRA, or other 340B discount is subsequently requested on that same utilization, the manufacturer can dispute that discount or rebate request without involving the covered entity, relieving covered entities of the burden and cost of becoming involved in such disputes.

75. In this way, Kalderos facilitates the provision of the statutory ceiling price for covered entities, while at the same time addressing circumstances where discounts or rebates on the same drug dispensed by the covered entity are or will be claimed. In an effort to head off duplicate discounts before they even are sought, Kalderos creates a ledger of the transactions for which 340B prices have been paid. The ledger is used to cross-check against the quarterly Medicaid file to ensure no duplicate Medicaid rebates will be paid. This mechanism addresses the federal regulators' failure to design a system to address duplicate Medicaid managed care rebates. Likewise, the prescription identification number can be used to identify prescriptions purchased by group

purchasing organizations from which some classes of covered entities cannot purchase 340B drugs or to identify prescribers that are not affiliated in any way with a covered entity. The claims information Kalderos collects is essential to performing these functions. Without it, Kalderos could not identify and prevent duplicate discounts and instances of diversion, leaving the 340B program broken.

76. The information requested by Kalderos is not burdensome for covered entities to provide. It is readily available information and matches what covered entities and their third-party administrators typically include when they attempt to "match" a drug dispensed to a 340B patient. It is also the very same information customarily provided in the pharmacy or healthcare claim submitted by the 340B covered entity to secure reimbursement for the drugs from a third-party payor, like the Medicaid or Medicare programs. *Cf. Novartis*, 102 F.4th at 463 (noting that "the burden of providing the claims data is 'minimal'"). The information requested by Kalderos also is customary when managed care entities, hospitals, physicians, retail pharmacies, group purchasing organizations, and States participating in the Medicaid program seek non-340B price concessions pursuant to price concession agreements with manufacturers or other pricing programs. In other words, when providing price concessions, manufacturers routinely seek the information necessary to confirm that program requirements for those price concessions are met. If 340B covered entities were permitted to refuse to provide such basic information, they would enjoy a preference over all other purchasers receiving price concessions. The statute does not require such a preference.

77. But Kalderos's solution also benefits 340B covered entities. In developing its solution, Kalderos worked closely with covered entities to identify the transaction points in the traditional system that created the greatest risk of a noncompliant transaction and to ensure that

feedback provided by covered entities was integrated.[8] The result is a solution that reduces burdens on covered entities through direct payments and a simple, intuitive, and easy-to-use platform.

78. In particular, covered entities will be able to request 340B pricing immediately after a drug dispense to a patient and be paid weekly, often before payment is required by a wholesaler and without needing to accumulate dispenses to a package size, which is necessary under the current practice. As such, covered entities will typically realize the 340B price faster than they do today. Further, because the Kalderos platform works directly with 340B covered entities and Medicaid rebates are requested on a time-lagged basis, often months in arrears, Kalderos's solution will allow 340B entities to routinely assert, receive, and validate their price concessions before a duplicate discount can arise. The need for a solution for the problem of duplicate discounts and rebates is even greater now in light of the discounts and rebates required under the IRA. Manufacturer disputes that arise thereafter will then, in the normal course, be focused on the Medicaid or Medicare programs, not the 340B covered entities.

E. HRSA's Policy Prohibiting All Conditions on Manufacturer Offers

79. Beginning in mid-2020, some drug manufacturers began imposing conditions on their offers to sell 340B drugs to covered entities at the statutory ceiling price. Among other conditions, several manufacturers required covered entities dispensing 340B drugs through contract pharmacies to provide claims data to third-party platforms.

80. On December 30, 2020, the General Counsel of HHS issued an Advisory Opinion on contract pharmacy arrangements under the 340B program. *See* HHS, *Advisory Opinion 20-06*

[8] In addition to working with covered entities and manufacturers, since inception, Kalderos has steadily built relationships with state Medicaid agencies, and now has relationships with Medicaid agencies in 49 States and the District of Columbia. Kalderos collaborates with state Medicaid agencies to identify and correct misapplied and duplicate discounts between 340B and Medicaid.

on Contract Pharmacies Under the 340B Program (Dec. 30, 2020). The Advisory Opinion focuses on the government's view that contract pharmacy arrangements must be honored under the statute, but it also states the following:

> In responding to a comment regarding perceived 340B violations, HRSA stated "[m]anufacturers cannot condition sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity." *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 82 Fed. Reg. 1210, 1223 (Jan. 5, 2017).

81. As noted above, a number of manufacturers filed suit arguing, in part, that the Advisory Opinion was unlawful. In the lawsuit brought by AstraZeneca, Judge Stark issued an Order on June 16, 2021 that, in part, rejects the governments arguments that "the Opinion merely restates a position that the government has held throughout the entirety of the 340B Program." *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, at 54–55 (D. Del. 2021). Judge Stark further stated that he found that "the Opinion is legally flawed." *Id*. at 59.

82. Two days after Judge Stark's Order, HHS withdrew the Advisory Opinion, purportedly "in light of ongoing confusion about the scope and impact of the Opinion." *See* HHS, *Notice of Withdrawal* (June 18, 2021). However, it is clear that the withdrawal did not reflect any change in HRSA policy. In the Notice, HHS stated that the "withdrawal of the Opinion does not impact the ongoing efforts of the Health Resources and Services Administration (HRSA) to enforce the obligations that 42 U.S.C. § 256b places on drug manufacturers." *Id.* Despite its withdrawal in the face of Judge Stark's criticism, the policies announced in the Advisory Opinion for the program as a whole continue to be HRSA's policy and its positions represent final agency action.

83. On May 17, 2021, Diana Espinosa, in her official capacity as Acting Administrator of HRSA, sent letters to various drug manufacturers declaring all conditions placed by manufacturers on their offers of 340B pricing unlawful. Three letters, in particular, were addressed to

manufacturers United Therapeutics, Sanofi, and Novartis, which had required covered entities dispensing 340B drugs though contract pharmacies to provide claims data as a condition of obtaining 340B pricing. As of this filing, the letters were posted on HRSA's website at https://www.hrsa.gov/opa/program-integrity/index.html. Although the letters are styled as statements to individual manufacturers, they are clearly policy statements that universally purport to prohibit any conditions of any kind, without regard to any individual fact or circumstance.

84. The substance of these three letters is identical. Each letter—without discussing or even citing HRSA's 1994 Guidance on manufacturer conditions—announced a new policy declaring unlawful *all* conditions placed by manufacturers on their offers to sell 340B drugs at the statutory ceiling price, including conditions requiring the production of claims data.

85. Further, the body of one of the letters is reproduced below, in relevant part, with emphasis added:

> The Health Resources and Services Administration (HRSA) has completed its review of United Therapeutics Corporation's (United Therapeutics) policy that places restrictions on 340B pricing to covered entities that dispense medication through pharmacies, unless the covered entities provide claims data to a third-party platform. After review of this policy and an analysis of the complaints HRSA has received from covered entities, HRSA has determined that United Therapeutics' actions have resulted in overcharges and are in direct violation of the 340B statute.
>
> Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers "shall…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." This requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. **Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities. Furthermore, the 340B statute does not permit manufacturers to impose conditions on covered entities' access to 340B pricing, including the production of claims data**.

86. In the wake of the May 17 letters, the manufacturers who received them each filed suit, challenging the agency's determination that manufacturers must provide 340B pricing on

drugs dispensed through contract pharmacies. *See supra*, n.1. United Therapeutics and Sanofi also challenged the agency's determination that manufacturers may not condition 340B prices on covered entities' production of claims data. *See United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-01686-DLF (D.D.C. June 23, 2021); *Sanofi-Aventis U.S., LLC v. HHS*, No. 3:21-cv-00634-FLW (D.N.J. Jan. 12, 2021). This action challenges only the latter determination; Kalderos takes no position on the contract pharmacy issue in this action.

87. On September 22, 2021, HRSA sent additional letters to manufacturers, including United Therapeutics, Sanofi, and Novartis, that reinforced the final nature of its unqualified policy pronouncements in the May 17, 2021 correspondence. Specifically, the matters discussed in the May 17, 2021 correspondence were referred to the OIG for enforcement, indicating that HRSA would not be rescinding its prior policy statements.

88. On October 4, 2021, HRSA sent another "violation" letter to another manufacturer. This more recent letter, indistinguishable from the May 17 letters cited above, also included the same broad, blanket policy declaration that "[n]othing in the 340B statute grants a manufacturer the right to place conditions" on covered entities 340B purchases.

F. Federal Appellate Decisions Striking Down HRSA's Policy

89. On May 21, 2024, the D.C. Circuit ruled that Defendants could not "categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities." *Novartis*, 102 F.4th at 464. The *Novartis* Court went on to hold that the disputed manufacturer conditions—including claims-data requirements—"do not violate section 340B on their face." *Id.*

90. Similarly, the Third Circuit in the *Sanofi* case also held that HRSA "overstepped the statute's bounds" by concluding that the 340B statute prevented manufacturers from imposing

any conditions on their offer of outpatient drugs to covered entities under the 340B program. *Sanofi v. HHS*, 58 F.4th 696, 707 (3d Cir. 2023). Like the D.C. Circuit, the Third Circuit ruled that the conditions adopted by the drug manufacturers in that case were "lawful." *Id.* at 704.

91. Defendants did not seek en banc reconsideration or petition for certiorari from the decisions in *Novartis* or in *Sanofi*.

G. Further Communications with HRSA About the Kalderos Platform

92. On August 7, 2024, Kalderos entered into an agreement with Eli Lilly & Company ("Lilly") through which Lilly would use the Kalderos platform to satisfy its obligations under the 340B statute.

93. On August 9, 2024, Kalderos communicated with HRSA concerning its platform, which requires covered entities to provide limited claims data and effectuates the 340B price through a direct cash rebate to covered entities. Email from Kalderos to HRSA (Aug. 9, 2024). Kalderos explained that its platform was to be launched with a manufacturer in the coming months. *Id.*

94. Kalderos made clear that, under its platform, claims-level data are exchanged between all parties, ensuring accurate and timely payment of discounts and preventing nearly 100% of non-compliant discounts. Kalderos further showed that its model builds in compliance checks that ensure that a covered entity is approved for 340B pricing and that duplicate discounts across all discount programs can be avoided. *Id.*

95. Kalderos also explained that developments relating to the Inflation Reduction Act ("IRA") and the 340B Alternative Dispute Resolution ("ADR") process "necessitate a transition to a 340B rebate model." *Id.* In addition, Kalderos highlighted that CMS has recognized in IRA guidance that a rebate model is necessary and appropriate to implement the Maximum Fair Price

while complying with the duplicate discount prohibitions built into the statute. *Id.* Kalderos pointed out that the new ADR regulations require manufacturers to obtain relevant information to support or defend an ADR claim, and that Kalderos's rebate model allows for the identification of that necessary information in an efficient manner that minimizes the requests made of covered entities or others. *Id.*

96. On September 4, 2024, Kalderos and Lilly presented the Kalderos platform to HRSA. They explained that the Kalderos platform was needed to comply with the 340B statute's prohibition against duplicate discounts and rebates and to implement the IRA. And they highlighted that the Kalderos platform was necessary to allow manufacturers to obtain data necessary to initiate or defend against ADR proceedings under the 340B statute.

97. Kalderos and Lilly underscored that the Kalderos platform was better for all stakeholders for multiple reasons. Under the platform, Lilly would issue rebates weekly, so covered entities would receive cash rebates directly within days of dispensing the 340B products. Under the existing replenishment model, dispensed products are acquired at the market price and are restocked with 340B priced replenishments, thereby requiring covered entities to wait until an entire product package is dispensed before they can obtain a replenishment product at the 340B price.

98. Under the Kalderos platform, moreover, the manufacturer and covered entity would have equal access to the same claims data thereby making the system more transparent and facilitating the identification of duplicate discounts and possible diversion. Kalderos and Lilly explained that the proposed effective date for implementing the Kalderos Platform would be November 1, 2024.

99. After the meeting on September 4, 2024, HRSA sent an email to Kalderos acknowledging the meeting to discuss "Kalderos' Direct Discount Platform--which would effectuate the 340B price directly to a covered entity as a rebate." E-mail from HRSA to Kalderos (Sept. 4, 2024). HRSA then stated that "[u]nder the 340B Program, the Pharmaceutical Pricing Agreement (PPA) is between the Secretary of HHS and the manufacturer" and "[t]o the extent a manufacturer would like to discuss its model for 340B pricing with HRSA, HRSA would engage with the manufacturer directly as it is a party to the PPA and responsible for compliance under the 340B Program." *Id.*

100. On September 5, 2024, Kalderos (i) thanked HRSA for "meeting with Kalderos and Lilly yesterday to discuss Kalderos' Direct Discount Platform," (ii) highlighted that the September 4th discussions "are just the most recent of many communications between Kalderos and the HRSA team, dating back to 2019, about Kalderos' Platform," and (iii) assured HRSA that the Kalderos platform continues to be a means "for ensuring the proper operation of the 340B Program for covered entities and manufacturers alike." E-mail from Kalderos to HRSA (Sept. 5, 2024).

101. On September 9, 2024, Lilly sent a follow-up letter to HRSA explaining its intention to satisfy its 340B obligation to provide a ceiling price through a rebate via a cash replenishment program, specifically using Kalderos' Truzo™ platform." Letter from Eli Lilly to HRSA (Sept. 9, 2024). Lilly expressed its hope that HRSA would "issue a statement endorsing Lilly's efforts to advance the cause of 340B--and broader government healthcare--program integrity." *Id.* at 1. Lilly highlighted that the "340B statute clearly states that rebates are a permissible form for offering and effectuating a 340B ceiling price." *Id.* at 3 (citing 42 U.S.C. § 256b(a)(1)). That is, "as a matter of law, the statutory requirement to offer covered entities covered outpatient drugs at the ceiling price can be effectuated either with an upfront discount or a post-purchase rebate." *Id.*

102. On September 18, 2024, HRSA sent Lilly a letter stating that implementation of the Kalderos platform would violate the 340B statute. *See* September 18 Decision at 1. HRSA stated that "the Secretary has not provided for such rebate as proposed by Lilly" and "[t]herefore, implementing such a proposal at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval of a rebate model such as Lilly has proposed." *Id.*

103. On September 23, 2024, Lilly conveyed its disappointment concerning HRSA's rejection of "Lilly's cash replenishment model and [HRSA's] determination that implementing a rebate model without affirmative approval would violate the 340B statute." Letter from Eli Lilly to HRSA (Sept. 23, 2024).[9] The letter further requested that HRSA inform Lilly by October 7th whether it had changed its position that the Kalderos platform was unlawful. *Id.* at 7. HRSA did not do so.

104. At the same time, on September 17, 2024, HRSA (i) informed another manufacturer that the 340B statute requires preapproval of a rebate before it can be implemented under the 340B program, and (ii) threatened that adoption of the rebate model would subject the manufacturer to cancelation of its Pharmaceutical Pricing Agreement and civil monetary penalties. Letter from HRSA to Johnson & Johnson at 2 (Sept. 17, 2024) ("September 17th Decision").[10]

ARTICLE III STANDING

105. Kalderos has Article III standing to bring this lawsuit. HRSA's policy prohibiting manufacturers from requiring the production of claims data, and its September 18 Decision cause Kalderos injury-in-fact, and a favorable decision by this Court would redress that injury.

[9] Lilly also provided responses to a series of questions posed by HRSA in its September 18, 2024 Letter. *Id.* at 1–7.

[10] On September 27, 2024, HRSA reiterated that "the 340B statute requires Secretarial approval of any rebate mechanism." Letter from HRSA to Johnson & Johnson at 1 (Sept. 27, 2024).

106. HRSA's policy and September 18 Decision directly injure Kalderos. Kalderos has entered into one or more agreements with drug manufacturers to implement their obligations under the 340B program. Under the agreements, Kalderos obtains compensation if its 340B platform is being used by drug manufacturers that contract with Kalderos. HRSA's policy and September 18 Decision injure Kalderos by declaring that its platform is inconsistent with the 340B statute.

107. To the extent that the agency prohibits manufacturers from requiring the collection of claims data, that determination causes injury to Kalderos. Without the claims data Kalderos collects from covered entities, the Kalderos platform cannot function. Consequently, if manufacturers cannot require covered entities to produce claims data, few, if any, manufacturers will contract or persist in a contractual arrangement with Kalderos. Likewise, if manufacturers are not permitted to offer the 340B pricing through a direct rebate to covered entities, then few if any manufacturers will contract with Kalderos for use of its platform.

108. This economic injury to Kalderos's business—caused by regulatory action that reduces the demand for Kalderos's solution and redressable by a decision from this Court setting aside that regulatory action—constitutes injury-in-fact under Article III. *See, e.g.*, *Clinton v. City of New York*, 524 U.S. 417, 432–33 (1998); *Am. Fuel & Petrochemical Mfrs. v. EPA*, 3 F.4th 373, 379–80 (D.C. Cir. 2021); *Airlines for Am. v. TSA*, 780 F.3d 409, 410–11 (D.C. Cir. 2015); *Energy & Env't Legal Inst. v. Epel*, 793 F.3d 1169, 1175 n.1 (10th Cir. 2015) (Gorsuch, J.); *Energy Future Coal. v. EPA*, 793 F.3d 141, 144–45 (D.C. Cir. 2015).[11]

[11] *Id.* ("The standing question in this case is straightforward: If the Government prohibits or impedes Company A from using Company B's product, does Company B have standing to sue? Suppose the FDA bans or makes it harder for soda manufacturers to use sugar. Does a sugar manufacturer have standing to sue? Or suppose the District of Columbia bans or makes it harder for concession stands to sell hot dogs. Does a local hot dog manufacturer have standing to sue? Ordinarily the answer to those questions is yes. In such cases, both Company A and Company B are

FINAL AGENCY ACTION

109. HRSA's policy prohibiting manufacturer conditions, first announced in its May 17, 2021 letters, is final agency action because it "mark[s] the 'consummation' of the agency's decisionmaking process" and is an action "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); *see Pharm. Rsch. & Mfrs. of Am. v. HHS*, 138 F. Supp. 3d 31, 39–47 (D.D.C. 2015). It is clear from the Advisory Opinion, the May 17 letters and their broad prohibition against the use of any conditions, and the referral to OIG, that HRSA has finally determined that, in its words, the 340B statute does "not permit manufacturers to impose conditions" of any kind, no matter how reasonable.

110. Likewise, HRSA's September 18 Decision is final agency action, which marks the consummation of the agency's decisionmaking process and determines legal rights. Although the September 18 Decision was issued to Lilly, Defendants were aware that Kalderos has contracted with Lilly to provide the use of its platform. HRSA's September 18 Decision directed to Lilly thus reflects HRSA's determination about the legality of the Kalderos platform under the 340B statute. Indeed, despite years of interactions between HRSA and Kalderos, on September 4, 2024, HRSA informed Kalderos that it would no longer deal directly with Kalderos, but instead would deal only with manufacturers that had entered into the PPA with the Secretary.

'an object of the action (or forgone action) at issue,' so 'there is ordinarily little question' that they have standing . . . .").

COUNT I: AGENCY ACTION IN EXCESS OF STATUTORY AUTHORITY
(5 U.S.C. § 706; 42 U.S.C. § 256b) (Prohibition of Claims Data)

111. Each of the foregoing paragraphs is incorporated by reference.

112. HRSA's policy prohibiting manufacturers from requiring production of basic claims data exceeds the scope of HRSA's statutory authority under Section 340B as the D.C. Circuit's analysis in *Novartis* makes clear.

113. Section 340B imposes only one requirement on drug manufacturers' offers to sell 340B drugs: Manufacturers must "offer each covered entity covered outpatient drugs for purchase at or below the applicable [statutory] ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). Kalderos's solution ensures that manufacturers offer 340B pricing when required under the statute. The statute precludes an entity from claiming covered entity status when duplicate discounts or diversion is present. *See id*. at § 256b(a)(4) ("[T]he term covered entity means an entity that meets the requirements described in paragraph (5)," which includes both duplicate discount prohibition and the diversion prohibition). HRSA has no authority to require the statutory ceiling price to be offered when the covered entity is not entitled to it.

114. Apart from imposing a statutory ceiling price, the text of Section 340B imposes no other requirements with regard to the terms and conditions on which drug manufacturers participating in the 340B Program may offer to sell covered outpatient drugs to covered entities. In particular, Section 340B does not prohibit drug manufacturers from requiring covered entities to provide claims data—e.g., the Rx number—as a condition of the manufacturers' offer to sell covered outpatient drugs at the statutory ceiling price.

115. At a minimum, Section 340B does not prohibit manufacturers from requiring covered entities to provide basic claims data where, as here, that information can be used to determine

whether the transaction is consistent with the statutory purposes to prevent duplicate discounts and diversion and does not impede covered entities' ability to access covered outpatient drugs at the statutory ceiling price, when they are, in fact, entitled to 340B pricing. 340B pricing is not owed where a duplicate discount or diversion is present. *See id*. § 256b(a)(4), (5). By statute, compliance with these prohibitions is required to entitle 340B covered entities to the ceiling price. *Id.*

116. HRSA's contrary reading of the statute reflected in its May 2021 letters conflicts with the statute's unambiguous terms and is arbitrary and capricious.

117. To the extent HRSA's policy rests on an assertion of authority to impose additional requirements over and above the statutory ceiling price required by Congress, this policy exceeds the agency's statutory authority. Apart from insisting upon a statutory ceiling price, Congress left it to the parties to address the terms and conditions of 340B sales. Accordingly, there is no "gap" in the statute for HRSA to fill, under the guise of "interpretation" or otherwise.

118. In any event, as this court has determined, HRSA also has no general "gap filling" authority to impose requirements that go beyond those set forth in the statute and PPA. *See Pharm. Rsch. & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 37–45 (D.D.C. 2014) (holding that HRSA lacks general rulemaking authority with regard to the 340B Program); *see also Novartis*, 102 F.4th at 456 ("The Secretary lacks rulemaking authority over the section 340B program"); *Sanofi*, 58 F.4th at 703 (same). As HRSA itself has recognized, it has no authority to enforce guidance "unless there is a clear violation of the 340B statute." Richard Church et al., K&L Gates LLP, *340B Update: HRSA Indicates it Lacks Authority to Enforce 340B Program Guidance* (July 23, 2020), https://www.jdsupra.com/legalnews/340b-update-hrsa-indicates-it-lacks-69793/.

119. HRSA's policy is therefore unlawful because it is "not in accordance with law" and "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A), (C).

120. Kalderos lacks an adequate remedy at law for Defendants' unlawful action.

COUNT II: ARBITRARY AND CAPRICIOUS AGENCY ACTION
(5 U.S.C. § 706; 42 U.S.C. § 256b) (Prohibition of Claims Data)

121. Each of the foregoing paragraphs is incorporated by reference.

122. HRSA's policy prohibiting manufacturers from requiring production of basic claims data is arbitrary and capricious.

123. HRSA's 1994 Guidance on manufacturer conditions does not prohibit manufacturer conditions in general or conditions requiring the production of claims data in particular. To the contrary, the agency's 1994 Guidance recognized that manufacturers are permitted to engage in "customary business practice[s], request standard information, [and] include other appropriate contract provisions" with regard to their 340B sales. 59 Fed. Reg. at 25,114; *see also id.* at 25,111–12 (stating that manufacturers may not "single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective"). The May 17, 2021 letters do not even cite the 1994 Guidance, let alone explain how the agency's policy can be reconciled with the 1994 Guidance or why the agency decided to depart from it. Nor do they address the other circumstances in which HRSA has permitted manufacturers to impose conditions on 340B sales to covered entities. HRSA's policy is thus an unexplained and unreasonable departure from the 1994 Guidance and the agency's past and current practice.

124. HRSA also failed to provide a reasoned explanation for its policy and to meaningfully grapple with significant aspects of the problem. HRSA did not explain how any statutory objective would be undermined by requiring covered entities to produce claims data that can be used to detect and prevent duplicate discounts and diversion in violation of the statute. HRSA did not address the significant threat to the integrity of the 340B Program posed by duplicate discounts and diversion or the extent to which manufacturer conditions requiring production of claims data,

such as Rx and prescriber identification numbers, could ameliorate that problem without impeding covered entities' ability to access 340B drugs at the statutory ceiling price. And HRSA did not explain why audits and administrative dispute resolution—after-the-fact mechanisms that to date have proven largely ineffective at ensuring compliance with statutory requirements—cannot be supplemented by prophylactic measures that help prevent duplicate discounts and diversion from occurring in the first place. Indeed, Kalderos was previously advised that HRSA had recommended to the Department that its model be acknowledged as entirely consistent with the 340B statute.

125. Claims data also are necessary to ensure compliance with the Inflation Reduction Act's requirements and to implement properly the 340B statute's ADR process. HRSA has arbitrarily and capriciously ignored these crucial considerations in opposing the claims-data requirement in the Kalderos platform.

126. HRSA's policy is therefore unlawful because it is "arbitrary, capricious, [and] an abuse of discretion." 5 U.S.C. § 706(2)(A).

127. Kalderos lacks an adequate remedy at law for Defendants' unlawful action.

COUNT III: AGENCY ACTION IN EXCESS OF STATUTORY AUTHORITY
(5 U.S.C. § 706; 42 U.S.C. § 256b) (Direct Rebates)

128. Each of the foregoing paragraphs is incorporated by reference.

129. HRSA's rejection of the Kalderos platform because it provides covered entities with the statutory ceiling price using a direct rebate is contrary to law.

130. In its September 18 Decision, HRSA imposed a preapproval requirement before a manufacturer may offer the ceiling price to covered entities through a rebate. *See* September 18 Decision at 1 ("To date, the Secretary has not provided for such rebate as proposed by Lilly. Therefore, implementing such a proposal at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval of a rebate model such as Lilly has

proposed.").

131. Similarly, in a related determination posted by HRSA on its website, HRSA stated that a rebate cannot be "tak[e]n into account" in "the amount required to be paid" to manufacturers, unless it has received preapproval by the Secretary. September 17th Decision at 2. HRSA continued that such rebates "violat[e] Section 340B(a)(1) of the PHS Act" because they require covered entities to purchase covered drugs "at prices that exceed 'the maximum price[s] that covered entities may permissibly be required to pay." *Id*.

132. These decisions are beyond the Secretary's authority under the 340B statute. The Secretary has no statutory authority to impose a preapproval requirement that operates to prohibit rebates to covered entities from manufacturers to effectuate the statutory ceiling price under the 340B statute. The 340B statute does not authorize HRSA to impose a preapproval requirement, to categorically prohibit manufacturers from offering the statutory ceiling price through rebates, or to disregard direct rebates provided to covered entities when assessing whether the requirements of the 340B statute have been met.

133. Indeed, the agency's position appears to be a back-door effort to dictate conditions on a manufacturer's *bona fide* offer of the 340B price to covered entities through a direct cash rebate. Multiple recent appellate court decisions have rejected HRSA's attempt to prohibit such conditions, affirming that Congress intended to allow "private parties" to "act freely" with respect to 340B delivery conditions. *See Novartis*, 102 F.4th at 460; *Sanofi*, 58 F.4th at 707. HRSA's misinterpretation of the 340B statute would circumvent these appellate decisions and use its purported authority to approve or disapprove of rebate/discount models to prevent manufacturers from imposing reasonable conditions on the *bona fide* offer of the 340B price.

134. HRSA's September 18 Decision is therefore unlawful because it is "not in accordance with law" and "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A), (C).

135. Kalderos lacks an adequate remedy at law for Defendants' unlawful action.

COUNT IV: ARBITRARY AND CAPRICIOUS AGENCY ACTION
(5 U.S.C. § 706; 42 U.S.C. § 256b) (Direct Rebates)

136. Each of the foregoing paragraphs is incorporated by reference.

137. HRSA's rejection of the Kalderos platform because it provides direct rebates to covered entities rather than up-front discounts is arbitrary and capricious.

138. *First*, the September 18 Decision offered no reasoned explanation for concluding that the Kalderos platform violates the 340B statute. Instead, HRSA stated that "the Secretary has not provided for such rebate as proposed by Lilly." September 18 Decision at 1 (stating that the 340B program "require[s] the approval of a rebate model such as Lilly has proposed"). The agency's bald statement that it has not "provided for such rebate as proposed by Lilly" is not reasoned decisionmaking.

139. *Second*, the agency has not and cannot offer any reasoned explanation for rejecting the Kalderos platform. Under the Kalderos platform, covered entities pay a market price to purchase covered outpatient drugs and provide limited claims data relating to those purchases. Purchases of covered outpatient drugs that qualify for the 340B discount trigger a rebate payment from the manufacturer directly to the covered entity and that rebate is timely, efficient, and transparent. In assessing whether the Kalderos platform complies with the 340B statute, it would be arbitrary and capricious for the Secretary to look solely to the initial market price paid for the covered outpatient drug while ignoring the direct rebate provided from the manufacturer to the covered entity designed that ensures that the covered entity pays no more than the ceiling price.

The Secretary's refusal to recognize a direct rebate from the manufacturer to the covered entity when assessing whether the manufacturer has complied with the 340B statute is arbitrary and capricious decisionmaking.

140. *Third*, the agency has not and cannot provide any reasoned basis for rejecting the Kalderos platform and requiring preapproval when the agency has allowed covered entities to employ a replenishment model, which operates through an after-the-fact sale of replenishment product at the 340B price following the purchase of a covered drug product at market prices. The replenishment model is a rebate model effectuated through subsequent purchases of covered products at the 340B price. The agency did not require or provide preapproval of the replenishment model, even though it involves after-the-fact rebates.

141. *Fourth*, the agency has failed to consider how its rejection of the Kalderos platform affects the ability of manufacturers to comply with their obligations under the 340B statute and also the requirements of the Inflation Reduction Act. The Kalderos model provides a mechanism through which illegal duplicate discounts within the 340B program and the IRA can be identified, avoided, and remedied after the fact if necessary. Nevertheless, the agency has disregarded the benefits of the Kalderos platform when it rejected its implementation in the September 18 Decision.

142. HRSA's September 18 Decision is therefore unlawful because it is "arbitrary, capricious, [and] an abuse of discretion." 5 U.S.C. § 706(2)(A).

143. Kalderos lacks an adequate remedy at law for Defendants' unlawful action.

PRAYER FOR RELIEF

Kalderos respectfully requests that the Court enter judgment in its favor and grant the following relief:

A. A declaration that HRSA's (i) policy prohibiting manufacturers from requiring covered entities to provide claims data and (ii) September 18 Decision are unlawful;

B. An order vacating HRSA's (i) policy prohibiting manufacturers from requiring covered entities to provide claims data and (ii) September 18 Decision;

C. An injunction barring Defendants from taking any enforcement action based on HRSA's (i) policy prohibiting manufacturers from requiring covered entities to provide claims data and (ii) September 18 Decision;

D. Attorney's fees and costs pursuant to 28 U.S.C. § 2412; and

E. Any other just and proper relief.

November 14, 2024

Respectfully Submitted,

/s/ Paul J. Zidlicky

SIDLEY AUSTIN LLP
Paul J. Zidlicky (No. 450196)
pzidlicky@sidley.com
(Tele.) 202-736-8013
Elizabeth Hardcastle (*pro hac vice* forthcoming)
ehardcastle@sidley.com
(Tele.) 202-736-8697
1501 K Street, N.W.
Washington, DC 20005
(202) 736-8000
(202) 736-8711 (fax)

Trevor L. Wear (*pro hac vice* forthcoming)
twear@sidley.com
(Tele.) 312-853-7101
One South Dearborn
Chicago, IL 60603
(312) 853-7000
(312) 853-7036 (fax)

Counsel for Plaintiff Kalderos, Inc.

Exhibit 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

KALDEROS, INC.
625 W. Adams Street, Suite 20-146
Chicago, IL 60661

Plaintiff,

v.

UNITED STATES OF AMERICA
~~950 Pennsylvania Avenue, NW~~
~~Washington, DC 20530~~

~~DIANA ESPINOSA, Acting~~
CAROLE JOHNSON, Administrator of U.S. Health Resources and Services Administration
5600 ~~Fisher~~Fishers Lane,
Rockville, MD ~~20825~~20852

U.S. HEALTH RESOURCES AND SERVICES ADMINISTRATION
5600 Fishers Lane,
Rockville, MD 20852

XAVIER BECERRA, Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, SW
Washington, DC 20201

Defendants.

Case No. 21-cv-2608 (DLF)

[PROPOSED] FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Kalderos, Inc., brings this suit against Defendants ~~Diana Espinosa~~Carole Johnson, in her official capacity as Acting Administrator of the U.S. Health Resources and Services

Administration; the U.S. Health Resources and Services Administration ("HRSA"); Xavier Becerra, in his official capacity as Secretary of the U.S. Department of Health and Human Services; and the U.S. Department of Health and Human Services ("HHS") (collectively, "Defendants"), and alleges as follows:

INTRODUCTION

1. This case involves the intersection of two federal healthcare programs—the 340B Program, so called after Section 340B of the Public Health Services Act, 42 U.S.C. § 256b, and the Medicaid Drug Rebate Program. In Section 340B, Congress required drug manufacturers to sell outpatient drugs to "covered entities" at a reduced price as a condition for their drugs to be covered by Medicaid. In the Medicaid Drug Rebate Program, Congress required drug manufacturers to pay rebates to States on their Medicaid drug purchases as a condition of Medicaid coverage. Both programs are immense—in 2020, manufacturers paid approximately $44 billion in 340B discounts, in addition to the more than $35 billion they pay annually in Medicaid rebates. In 2022, manufacturers paid in excess of $52 billion in 340B discounts.

2. Recognizing that it would be unfair and unsustainable to require manufacturers to provide *both* a 340B price *and* a Medicaid rebate on the same unit for a drug dispensed to a patient of a 340B covered entity who is also a Medicaid beneficiary, Congress prohibited such "duplicate discounts." *See* 42 U.S.C. §§ 256b(a)(5)(A)(i), 1396r-8(j)(1). In addition, Congress prohibited covered entities from diverting, *i.e.*, reselling or otherwise transferring, 340B drugs to persons who are not patients of the covered entity. *See id.* § 256b(a)(5)(B).

3. Unfortunately, despite the statute's balanced design intended both to provide the 340B price to covered entities and to prevent duplicate discounts and diversion, the 340B ~~Pro-gram~~program is fundamentally broken. In direct contravention of the statute, duplicate discounts

and diversion of 340B drugs represent significant, ongoing problems for the 340B ~~Program~~program. As documented in a series of recent reports by the Governmental Accountability Office ("GAO"), developments over the last decade and weaknesses in federal oversight have caused these problems to grow unchecked, undermining the integrity of both programs. HRSA, the unit of HHS responsible for administering the 340B Program, has proven either unwilling or unable to address these concerns.

4. As a result, manufacturers are concerned that some covered entities are engaged in unchecked violations of the duplicate discount and diversion prohibitions. Multiple lawsuits ~~are currently pending~~were filed in multiple districts involving allegations by manufacturers that they are not obligated to make 340B prices available in connection with a covered entity's use of contract pharmacies, by which the manufacturers allege that the covered entities are responsible for both duplicate discounts and diversion.[1]

5. Covered entities and their representatives, for their part, have contended that manufacturers are not providing required 340B pricing. The 340B ~~Program~~program thus faces a crisis of confidence, where neither manufacturers nor covered entities believe their counterparts are acting in the manner required by statute.

---

[1] *See Sanofi-Aventis U.S., LLC v. ~~U.S. Dep't of Health & Hum. Servs.,~~HHS*, No. 3:21-cv-634-FLW (D.N.J. Jan. 12, 2021), *rev'd in part, affirmed in part*, *Sanofi Aventis U.S., LLC v. HHS*, 58 F.4th 696, 707 (3d Cir. 2023); *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-81-SEB-MJD (S.D. Ind. Jan. 12, 2021), *appeal docketed*, No. 21-3128 (7th Cir. 2021); *AstraZeneca Pharms. LP v. Becerra*, No. 1:21-cv-27 (D. Del. Jan. 12, 2021), *aff'd sub nom. Sanofi Aventis U.S., LLC v. HHS*, 58 F.4th 696, 707 (3d Cir. 2023); *Novo Nordisk, Inc. v. ~~U.S. Dep't of Health & Hum. Servs.,~~HHS*, No. 3:21-cv-806 (D.N.J. Jan. 15, 2021), *rev'd in part, aff'd in part*, *Sanofi Aventis U.S., LLC v. HHS*, 58 F.4th 696, 707 (3d Cir. 2023); *Novartis Pharms. Corp. v. Espinosa*, No. 1:21-01479-DLF (D.D.C. May 31, 2021), *aff'd* 102 F.4th 452 (D.C. Cir. 2024); *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-01686-DLF (D.D.C. June 23, 2021~~.~~), *aff'd sub nom. Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. 2024).

6. Plaintiff Kalderos, a technology company serving the healthcare industry, has developed an equitable, easy-to-use technology platform designed to ensure that 340B covered entities have confidence they are receiving the 340B prices to which they are entitled and that manufacturers have confidence they will not be subject to duplicate discounts and have some means to address diversion concerns. In this regard, Kalderos seeks to be an honest broker and to assist both covered entities and manufacturers in being able to have their reasonable expectations met, with the goal of restoring both sides' confidence in the program. In short, Kalderos seeks to administer 340B transactions in an efficient, legally compliant manner to the benefit of all stakeholders.

7. Specifically, Kalderos developed its electronic platform as a mechanism to administer 340B pricing. Covered entities would use ~~Kalderos's~~the Kalderos platform to share a minimum number of data elements on utilization ~~when~~where they wish to request the statutory ceiling price from manufacturers working with Kalderos. When requesting the 340B price, covered entities would provide ~~to~~ Kalderos certain minimal claims information, including the drug's prescription or Rx number, the prescriber identification number, and other basic information. This information allows Kalderos to identify and prevent multiple discounts being provided on the same prescription and to prevent various forms of diversion in violation of the statute. Providing this information is not burdensome for covered entities. Prescription and prescriber identification is routinely secured in determining the appropriateness of pricing in managed care, pharmacy benefit manager, retail pharmacy, hospital, physician, and group purchasing organization contracts. This information also is commonly collected and maintained in an easily shareable format by covered entities or their third-party administrators to identify drug utilization that is potentially eligible for 340B pricing. Use of the Kalderos platform would be a condition required by manufacturers choosing to work with Kalderos for transactions ~~involving contract pharmacies~~under the 340B statute.

8. Under the Kalderos platform, covered entities would receive 340B pricing through a direct cash rebate from manufacturers. The platform's rebate process implements the 340B statute by ensuring that a manufacturer is not paid more than the ceiling price by the covered entity. Specifically, because the rebates under the Kalderos platform are provided directly to covered entities in an efficient, timely, and transparent manner, there is no lawful basis for ignoring them when assessing whether the manufacturer was paid more than the ceiling price.

~~8.~~9. Kalderos has communicated with the Office of Pharmacy Affairs ("OPA") at HRSA and the Department over 20 times beginning in ~~a two and a half year span~~April 2019 to describe its solution and answer both OPA's and the Department's questions in detail. OPA and the Department assured Kalderos that they were considering Kalderos's model and would provide their analysis to Kalderos. Kalderos repeatedly stated to OPA and the Department that the manufacturers with which it expected to contract would need an assurance from Defendants that those manufacturers would be permitted, as a condition of making 340B pricing available, to require use of the Kalderos platform. Kalderos repeatedly stressed to Defendants that it was being prevented from launching and effectively marketing its solution because manufacturers had not been advised by Defendants that Kalderos's conditions of use were permissible. Kalderos was told that OPA had recommended in a memorandum to the Department that the Kalderos model be permitted.

~~9.~~10. In May 2021, however, HRSA abruptly announced an unqualified, absolute policy that no conditions—no matter how reasonable—could be imposed on the issuance of a 340B price. Under this ~~new~~ policy, announced in a series of letters issued to manufacturers on May 17, 2021, manufacturers may not require covered entities to provide any claims information when requesting the statutory ceiling price, no matter how regularly it is supplied in verifying other, non-340B pricing throughout the healthcare industry. HRSA threatened manufacturers with enforcement

action and civil monetary penalties if they did not immediately comply with HRSA's ~~new~~ policy prohibiting the conditioning of 340B prices on the provision of claims data by covered entities.

~~10.~~11. In light of HRSA's ~~new~~ blanket policy forbidding manufacturer conditions, Kalderos ~~has~~was largely ~~been~~ unable to move forward with its model, with multiple manufacturers stating that they would contract with Kalderos for services, but ~~cannot~~could not in light of Defendants' policy position. Accordingly, having unsuccessfully engaged with Defendants for more than 30 months, Kalderos ~~now brings~~brought this action under the Administrative Procedure Act ("APA") to challenge the unlawful and arbitrary and capricious policy articulated in the May 17, 2021 letters.[2]

12. On January 28, 2022, this Court granted a stay in this case pending the D.C. Circuit's decision in *Novartis Pharmaceuticals Corp. v.* ~~HRSA's new policy is unlawful because it exceeds the agency's statutory authority. Nothing in Section 340B prohibits~~*Espinosa*, No. 21-5299, and *United Therapeutics Corp. v. Espinosa*, No. 21-5304. *See* Order [D.E. 26] at 1 (Jan. 28, 2002). In doing so, this Court observed that (1) "the D.C. Circuit's ruling in *Novartis* will not answer all questions present in this case," *id.* at 2, but (2) it "could impact the resolution of Kalderos's claims," *id.* at 3. Both observations proved correct.

13. On May 21, 2024, the D.C. Circuit rejected HRSA's position that "section 340B prohibits drug manufacturers from imposing any conditions on the distribution of discounted drugs to covered entities." *Novartis v. Johnson,* 102 F.4th 452, 459 (D.D.C. 2024). With respect to the specific conditions identified by the manufacturers—including a claims data requirement—the

~~[2] In the May 17, 2021 letters, HRSA also concluded that the 340B statute requires drug manufacturers to provide 340B pricing on drugs dispensed by contract pharmacies. Kalderos takes no position on that issue. This action challenges only HRSA's conclusion that drug manufacturers may not condition the availability of 340B prices on the production of claims data. Manufacturers using the Kalderos platform can use the platform to honor contract pharmacy transactions.~~

D.C. Circuit held, based upon the record before the court, that the conditions "do not violate section 340B on their face." *Id.* at 463–64.

14. Relying on the D.C. Circuit's decision in *Novartis*, Kalderos undertook further steps to ensure that manufacturers could adopt its platform. On August 7, 2024, Kalderos entered into an agreement with Eli Lilly & Company ("Lilly") through which Lilly would use the Kalderos platform to satisfy its obligations under the 340B statute.

15. In August and September 2024, Lilly and Kalderos communicated with HRSA concerning the Kalderos platform. They explained that the Kalderos platform (i) requires the submission of claims data from covered entities (to provide transparency and prevent duplicate discounts and diversion) and (ii) provides covered entities a direct cash rebate to ensure that they receive 340B pricing. Under the Kalderos platform, covered entities would receive a direct rebate from the manufacturer on eligible 340B drug purchases within seven days of submitting the necessary claims data.

16. On September 18, 2024, HRSA sent Lilly a letter stating that adoption of the Kalderos platform "would be inconsistent with the statutory requirements for the 340B Program, which require the approval of a rebate model such as Lilly has proposed." Letter from HRSA to Eli Lilly at 1 (Sept. 18, 2024) ("September 18 Decision").

17. Around the same time, HRSA rejected another manufacturer's proposal to provide the 340B ceiling price through a rebate, threatening that doing so would subject the manufacturer to cancelation of its Pharmaceutical Pricing Agreement ("PPA") and civil monetary penalties.

~~11.~~18. HRSA's rejection of the Kalderos platform is contrary to law and arbitrary and capricious. *First*, insofar as HRSA rejected the Kalderos platform because it requires claims data, the agency's action was contrary to law. As *Novartis* recognized, section 340B does not prohibit

manufactures from requiring covered entities to provide basic claims information, including the Rx number and prescriber identification number, as a condition of their offers to sell 340B drugs at the statutory ceiling price. ~~HRSA's contrary interpretation has no basis in the statutory text and improperly imposes requirements that Congress did not include in the statute. Apart from requiring that the ceiling price be offered to 340B covered entities, the statute leaves the terms and conditions of 340B sales to the parties.~~

19. ~~There is thus no "gap" in the statute for HRSA to fill regarding manufacturer conditions. And, in any event, Congress has not granted HRSA "gap filling" authority under Section 340B. *See PhRMA*~~To the contrary, collection of basic claims data is necessary to the proper operation of the 340B statute by allowing manufacturers and covered entities to identify and avoid duplicate discounts and diversion and to implement properly the 340B statute's Administrative Dispute Resolution ("ADR") process. 42 U.S.C. § 256b(d)(3).

20. HRSA's claims-data based objection is also arbitrary and capricious. HRSA previously issued guidance in 1994 that allowed manufacturers to "request standard information" from covered entities as a delivery condition. HRSA has arbitrarily departed from that policy without a reasoned explanation and without grappling with the crucial role that claims-data requirements serve in preventing duplicate discounts and diversion.

21. *Second*, HRSA's rejection of the Kalderos platform because it allows for direct rebates violates the 340B statute and is arbitrary and capricious. The 340B statute expressly authorizes drug manufacturers to offer the 340B ceiling price through rebates or discounts to covered entities. 42 U.S.C. § 256b(a)(1). Nothing in the statute gives HRSA authority to demand preapproval of a manufacturer's provision of the ceiling price, whether that be through a rebate or a discount.

22. As with HRSA's opposition to claims-data requirements, HRSA's policy rejecting rebates also is arbitrary and capricious. HRSA has widely permitted, without prior authorization, rebates in the form of product replenishment for a number of years and has described that model in court filings. HRSA also has previously recognized that manufacturers may take into account rebates in offering the statutory ceiling price under the 340B program. *See* 1998 Guidance, 63 Fed. Reg. 35,239, 35,242 (June 29, 1998). HRSA has failed to provide a reasoned explanation for its policy or its rejection of the Kalderos platform.

~~12.~~ In line with the D.C. Circuit's decision in *Novartis*, the ~~v. *HHS*, 43 F. Supp. 3d 28, 45 (D.D.C. 2014) ("Congress has not given HHS the broad rulemaking authority"). This Court has, in fact, held that HRSA's rulemaking authority is limited to three discrete areas, not relevant here. *See id.* at 41 (holding "Congress specifically authorized rulemaking in three places: (1) the establishment of an administrative dispute resolution process, (2) the 'regulatory issuance' of precisely defined standards of methodology for calculation of ceiling prices, and (3) the imposition of monetary civil sanctions"). OPA has accepted this Court's ruling in that regard, conceding that it can only enforce "clear" violations of the statute. *See* Richard Church et al., K&L Gates LLP, *340B Update: HRSA Indicates it Lacks Authority to Enforce 340B Program Guidance* (July 23, 2020), https://www.jdsupra.com/legalnews/340b-update-hrsa-indicates-it-lacks-69793/.~~

~~13. HRSA's new policy also is arbitrary and capricious because HRSA departed, without explanation, from the agency's prior guidance on manufacturer conditions. The guidance HRSA issued in 1994 allowed manufacturers to employ "customary business practices," "request standard information," and adopt "appropriate contract conditions." HRSA's position that the statute does not permit manufacturers to impose any conditions is also inconsistent with the agency's own current practices. HRSA has long allowed manufacturers to impose conditions on covered~~

~~entities' 340B purchases in other contexts, such as when a particular drug is in limited supply. HRSA's new policy also is arbitrary and capricious because HRSA failed to provide a reasoned explanation for its new policy and did not meaningfully grapple with significant aspects of the problem, including the compelling need to prevent unlawful duplicate discounts and diversion.~~

~~14.~~23. ~~The~~ Court should ~~set aside HRSA's new policy against manufacturer conditions and~~now make clear that manufacturers may require covered entities seeking the 340B ceiling price to provide the basic claims information needed (1) to prevent duplicate discounts and diversion, (2) to restore the confidence that covered entities are, in fact, receiving the prices to which they are entitled, and (3) to ensure the integrity of the 340B ~~Program~~program as envisioned by Congress.

24. The Court also should reject the agency's determination that rebates violate the 340B statute because they require covered entities to pay more than the statutory ceiling price. That position is contrary to the statute. Indeed, Defendants have permitted rebates as a method to provide the statutory ceiling price under the 340B statute. Defendants cannot and should not prohibit the Kalderos platform, which ensures that the 340B discount price is offered to covered entities through a direct cash rebate and that manufacturers are not required to provide duplicate discounts or discounts in cases of drug diversion in violation of the 340B statute.

PARTIES

~~15.~~25. Plaintiff Kalderos, Inc. is a technology company focused on solving the problems facing the United States healthcare system. Kalderos is a Delaware corporation with its principal place of business at 625 West Adams Street, Suite 20-146, Chicago, IL 60661.

~~16.~~26. ~~Diana Espinosa~~Carole Johnson is the ~~Acting~~ Administrator of HRSA.[3] In that capacity, she has ultimate responsibility for activities at HRSA, including the actions complained of herein. She is being sued in her official capacity only.

~~17.~~27. HRSA is an agency of the United States and a division of HHS. Its headquarters and principal place of business are at 5600 Fishers Lane, Rockville, MD 20852.

~~18.~~28. Xavier Becerra is the Secretary of HHS. In this capacity, he has ultimate responsibility for activities at HHS, including the actions complained of herein. He is being sued in his official capacity only.

~~19.~~29. HHS is a department of the United States. HHS oversees the activities of HRSA. HHS's headquarters and principal place of business are at 200 Independence Avenue SW, Washington, DC 20201.

JURISDICTION AND VENUE

~~20.~~30. Kalderos brings this action pursuant to the APA, 5 U.S.C. §§ 701–706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202.

~~21.~~31. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1361.

[3] "[T]he United States may be named as a defendant in any [APA] action, and a judgment or decree may be entered against the United States: *Provided*, That any mandatory or injunctive decree shall specify the Federal officer or officers (by name or by title), and their successors in office, personally responsible for compliance." 5 U.S.C. § 702.

~~22.~~32. The Court has authority to grant the relief requested by Kalderos pursuant to the APA, 5 U.S.C. §§ 701–706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202.

~~23.~~33. Venue is proper in this District pursuant to 28 U.S.C. § 1391(e)(1) because at least one Defendant is an officer or agency of the United States and resides in this District.

GENERAL ALLEGATIONS

A. The 340B Program

~~24.~~34. Congress established the 340B Program in 1992. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585 § 602(a), 106 Stat. 4943, 4967 (adding Section 340B to the Public Health Service Act, codified at 42 U.S.C. § 256b); *see* H.R. Rep. No. 102-384 (II), at 11–13 (1992).

~~25.~~35. "The 340B Program is tied to the earlier-enacted, much larger Medicaid Drug Rebate Program." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 114 (2011). Medicaid is a cooperative federal-state program through which the federal government provides financial assistance to States so that they may furnish medical care to needy individuals. *See* 42 U.S.C. § 1396 *et seq.* Enacted in 1990, the Medicaid Drug Rebate Program allows drug manufacturers to obtain coverage for their drugs under Medicare Part B and Medicaid if they enter into an agreement with HHS to provide rebates to States that are generally intended to give States the "'best' prices" on their Medicaid drug purchases. *See Astra*, 563 U.S. at 114–15 (citing 42 U.S.C. § 1396r-8(a)).

~~26.~~36. After enactment of the Medicaid Drug Rebate Program, manufacturers could no longer provide voluntary discounts to safety net hospitals and clinics that had pharmacies and dispensed outpatient drugs to their patients, without affecting their Medicaid rebate payments. As a result, manufacturers stopped providing the discounts that they had previously offered. Congress established the 340B Program to ensure that these entities, now called "covered entities," could have discounted medications restored, carving out the discounts manufacturers offered to covered

entities from the Medicaid "best price" calculation. *See* 42 U.S.C. §§ 256b, 1396r-8(c)(1)(C)(i~~)(I~~); *see also* H.R. Rep. No. 102-~~84~~384 (II), at 11–12 ("The Committee expects that this exemption will remove any disincentive that the Medicaid rebate program creates to discourage manufacturers from providing substantial voluntary or negotiated discounts to these clinics, programs, and hospitals.").

~~27.~~37. The 340B Program requires drug manufacturers to sell certain outpatient drugs to covered entities at reduced prices; in return, manufacturers can have their drugs covered by Medicaid. *See Astra*, 563 U.S. at 113, 115–16; 42 U.S.C. § 1396r-8(a)(1), (5). ~~Specifically,~~ Section 340B directs the Secretary of HHS to enter into agreements with drug manufacturers under which the amount required to be paid by covered entities for "covered outpatient drugs" must not exceed a "ceiling price" calculated pursuant to a formula set forth in the statute. *See* 42 U.S.C. § 256b(a)(1)–(2). Paragraph (a)(1) provides that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2)." *Id.* "Covered outpatient drugs" are defined by reference to the drugs subject to the Medicaid Drug Rebate Program. *See id*. §§ 256b(b), 1396r-8(k)(2).

~~28.~~38. By statute, the agreement between the drug manufacturer and HHS, referred to as a Pharmaceutical Pricing Agreement ("PPA"), must "require 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." The PPAs "simply incorporate

statutory obligations and record the manufacturers' agreement to abide by them." *Astra*, 563 U.S. at 118. "The statutory and contractual obligations … are one and the same." *Id.*

~~29.~~39. Section 340B also imposes certain obligations on covered entities participating in the program. To qualify as a "covered entity," the entity must be one of the fifteen types of entities enumerated in Section 340B(a)(4), such as "critical access" hospitals serving rural communities, "disproportionate share" hospitals serving a disproportionate number of low-income patients, and certain community health centers. *See* 42 U.S.C. § 256b(a)(4). In addition, the covered entity must "mee[t] the requirements described in paragraph (5)." *Id.*

~~30.~~40. Paragraph (5) prohibits covered entities from (1) requesting payment under Medicaid for drugs subject to an agreement under Section 340B if the drug is also subject to the payment of a rebate under Medicaid (the "duplicate discount" prohibition), *id.* § 256b(a)(5)(A)(i), and (2) reselling or otherwise transferring a drug subject to an agreement under Section 340B to a person who is not a patient of the covered entity (the "diversion" prohibition), *id.* § 256b(a)(5)(B).

~~31.~~41. Although covered entities are subject to audits by HRSA and manufacturers for compliance with the prohibitions on duplicate discounts and diversion, *id.* § ~~257b~~256b(a)(5)(C), these retrospective remedies ~~(none of which is available to Kalderos)~~ have proven quite clearly deficient and almost entirely ineffective at preventing violations, and nothing in the statute precludes the adoption of prophylactic measures to prevent duplicate discounts and diversion.

B. HRSA's Guidance on Manufacturer Conditions

~~32.~~42. Section 340B specifies only that manufacturers must offer to sell covered drugs at the ceiling price specified in the statute~~,~~ if other customers are offered such drugs. The statute otherwise does not restrict the terms and conditions for 340B sales, which manufacturers and 340B covered entities may determine for themselves through negotiation.

~~33.~~43. In 1994, HRSA issued guidance addressing conditions that manufacturers may place on their offers to sell 340B drugs to covered entities at the ceiling price. Without citing statutory authority or a statutory basis, the guidance provides that "[a] manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions." 59 Fed. Reg. 25,110, 25,113 (May 13, 1994) ("1994 Guidance"). The 1994 Guidance enumerates five categories of "assurances" that "may not be required": "(1) eligibility to participate in the program; (2) utilization of covered outpatient drugs only in authorized services; (3) maintaining the confidentiality of the drug pricing information; (4) permitting the manufacturers to audit purchase, inventory, and related records prior to the publication of approved ~~...~~. . . guidelines; and (5) submitting information related to drug acquisition, purchase, and inventory systems." *Id.* at 25,113–14. The agency further stated that "[m]anufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective," or "place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program." *Id.* at 25,113.

~~34.~~44. Although HRSA failed to establish how the 1994 Guidance was itself authorized by the statute, the 1994 Guidance did not, in any event, purport to prohibit all manufacturer conditions. To the contrary, it provided that manufacturers were permitted to "include provisions that address customary business practice, request standard information, or include other appropriate contract provisions." *Id.* at 25,114. The 1994 Guidance also explained that "[i]f a manufacturer asks a covered entity whether the entity is in fact participating in the Section 340B discount program, the entity must supply the manufacturer with this information." *Id.* ~~at 25,114.~~

~~35.~~45. In addition, HRSA has long acknowledged that manufacturers can impose certain conditions on 340B sales. For instance, HRSA permits manufacturers to impose a condition that,

to secure a 340B price, a covered entity must enroll with an intermediary, called a wholesaler, and seek reduced 340B prices only through that mechanism. Enrollment with a wholesaler requires covered entities to meet certain conditions. These conditions may include a credit check, minimum purchasing obligations~~, estimate of monthly purchases~~, account set-up forms, copies of balance sheets, income statements, tax information, vendor statements, a voided check, copies of licenses, a contract with wet signature, and a security interest in covered entity personal property. All of these conditions are more demanding than those that would be required to collaborate with Kalderos. Further, many of the conditions wholesalers impose are the same as those sought by Kalderos, including the use of a web-based ordering and financial system with unique user ID and password.

~~36.~~46. As another example, HRSA has long acknowledged that manufacturers can impose a condition that covered entities must purchase through a limited set of distribution points, or even a single distribution point, when limited supply of a product is available, in order to control a shortage risk or to prevent covered entities from attempting to capitalize inappropriately on the "spread" between a very low 340B price and a much higher reimbursement from a third-party payor. *See* HRSA, Clarification of Non-Discrimination Policy (May 23, 2012) (policy on "manufacturer limitations or conditions on sales of covered outpatient drugs to eligible 340B ~~[covered]~~ entities," ~~permitting~~ stating that "manufacturers ~~"~~have the ability to develop alternate allocation procedures during situations when the available supply of a covered drug is not adequate to meet market demands").

~~37.~~47. The HRSA website contains multiple notices by manufacturers issued over a number of years that HRSA has reviewed and that impose limited distribution systems. *See* HRSA, *Manufacturer Notices to Covered Entities*, https://www.hrsa.gov/opa/manufacturer-notices/index.html (last visited Oct. ~~6, 2021~~15, 2024) (including limited distribution network conditions

from 9 manufactures in 2021 alone and limited distribution network conditions imposed by over 25 manufacturers in 2020). HRSA not only has not forbidden such conditions, but has facilitated manufacturer communication of these conditions and refused to support some covered entities in their opposition to these programs, stating that these conditions are consistent with the statute.

~~38.~~48. Although HRSA has requested advance notice of these conditions, it has not stated that manufacturers are required to provide such notice, or to obtain HRSA approval, before imposing such conditions. *See* HRSA, *Clarification of Non-Discrimination Policy* (May 23, 2012) (stating that "[a]lthough prior notification by manufacturers is not currently required, HRSA believes that voluntarily providing OPA with timely notification will benefit manufacturers as well as covered entities by reducing the chance for misunderstandings about the requirements of the 340B Program and lessen the potential for disputes").

C. The Problem of Duplicate Discounts and Diversion

~~39.~~49. Duplicate discounts and diversion are ~~a~~ significant ~~challenge~~challenges to the integrity of the 340 Program, and manufacturers have a legitimate interest in addressing these issues through reasonable conditions designed to ensure compliance with statutory requirements.

~~40.~~50. A duplicate discount occurs when a manufacturer sells a covered drug to a covered entity at the 340B ceiling price and then also is invoiced for a Medicaid rebate on the same unit. Because the 340B price reduction and the Medicaid rebate can *each* be as much as 50 percent of a drug's cost, or even more, manufacturers subjected to duplicate discounts incur significant financial losses. ~~This in turn contributes to the cost of prescription drugs for everyone, as duplicate~~A duplicate discount also may occur when the same covered entity seeks a second discount on the same 340B covered drug purchase, or multiple different covered entities each request 340B discounts on the same covered drug purchase. In addition, as a result of the Inflation Reduction Act,

there is a risk of duplicate discounts between the 340B price and the Maximum Fair Price ("MFP"), or even triplicate discounts among 340B, MFP, and Medicaid rebates when the patient of a covered entity is eligible for both Medicare and Medicaid. This in turn contributes to the cost of prescription drugs for everyone, as duplicate or triplicate discounts, once provided, can only rarely be secured back by the manufacturers.

~~41.~~51. Diversion occurs when a covered entity resells or transfers a drug subject to a 340B agreement to a person who is not a patient of the covered entity. This may happen, for example, when 340B drugs are given to individuals who are not receiving healthcare services from the covered entity or are receiving services that are not consistent with the type of services for which the covered entity qualified for 340B status. Certain covered entities also are not permitted to purchase 340B drugs through group purchasing organizations, which secure their own discounts from manufacturers. *See* 42 U.S.C. § 256b(a)(4)(L)(iii). Diversion harms manufacturers by requiring them to provide price reductions on transactions that fall outside the 340B ~~Program~~program, again increasing the cost of prescription drugs for everyone.

~~42.~~52. Recognizing these problems, Congress prohibited covered entities from subjecting manufacturers to duplicate discounts by requesting payment under Medicaid for 340B drugs that also are subject to a rebate under the Medicaid Drug Rebate Program. *See id.* § 256b(a)(5)(A)(i). Congress similarly prohibited covered entities from diverting 340B drugs. *See id.* § 256b(a)(5)(B).

~~43.~~53. Congress further directed the Secretary to "establish a mechanism to ensure that covered entities comply with" the prohibition on duplicate discounts, *id.* § 256b(a)(5)(A)(ii), and to "provide for improvements in compliance by covered entities with the requirements of [Section 340B] in order to prevent diversion and violations of the duplicate discount provision," *id.* § 256b(d)(2)(A), including by developing "detailed guidance describing methodologies and

options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts," *id.* § 256b(d)(2)(B)(iii).

~~44.~~54. Despite Congress's expressed concern about duplicate discounts and diversion and the threat they pose to the integrity of the 340B Program, HRSA has failed to live up to its statutory obligations, and duplicate discounts and diversion remain ~~a~~ significant ~~problem~~problems for the 340B ~~Program. In the last three years, the~~program. The Government Accountability Office ("GAO"), for instance, has issued multiple reports detailing serious shortcomings in HRSA's efforts to prevent violations. *See* GAO, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (June 2018) ("2018 GAO Report~~);~~"); GAO, *340B Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* (Jan. 2020) ("January 2020 GAO Report"); GAO, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements* (Dec. 2020) ("December 2020 GAO Report").

~~45.~~55. In its most comprehensive report on the subject of duplicate discounts, GAO concluded that "HHS does not have reasonable assurance that states and covered entities are complying with the prohibition on duplicate discounts," January 2020 GAO Report, ~~"What GAO Found"~~ leaving "drug manufacturers at risk of providing duplicate discounts" and "compromis[ing] the integrity of the 340B Program." *Id.* at 27.[4]

[4] These conclusions echo similar findings regarding duplicate discounts reflected in other government reports and testimony. *See also* GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 at 31, tbl. 2 (Sept. 2011) (recommending that HRSA "[d]evelop more detailed guidance on the procedures covered entities can follow to avoid the Medicaid duplicate discount"); OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 2 (Feb~~.~~ 4, 2014) (finding that "most covered entities in [the] study do not conduct all of the oversight activities recommended by HRSA" to prevent duplicate discounts); House Energy & Commerce Committee, *Review of the 340B Drug Pricing Program*

~~46.~~56. GAO explained that "[i]n recent years, the potential for duplicate discounts has increased due to substantial growth in the 340B Program and the expansion of the Medicaid Drug Rebate Program" in 2010 to include drugs provided under Medicaid managed care in addition to drugs provided under Medicaid fee-for-service. *Id.* at 2–3.[5] "Specifically, from 2010 to 2019, the number of covered entities participating in the 340B ~~Program~~program increased from nearly 9,700 to nearly 13,000." *Id.* at 2. And the number of "contract pharmacies" dispensing 340B drugs "increased from about 1,300 at the beginning of 2010 to around 23,000 in 2019." *Id.*[6] As a result of these developments, "total Medicaid drug rebates more than doubled from about $15 billion in fiscal year 2011 to more than $36 billion in fiscal year 2018." *Id.* at 3.

~~47.~~57. GAO found "several areas of weakness in HRSA's oversight processes that impede its ability to ensure that duplicate discounts are prevented or remedied." *Id.* at 23. For example,

---

at 37 (Jan. 10, 2018) (explaining that "duplicate discounts" are a "growing problem" whose "volume" "may be far greater than has been previously realized" and that "some covered entities fail to adequately protect against the risk of duplicate discounts"); OIG, *Testimony before the United States Senate on Health, Education, Labor, and Pensions* at 3–4, 5 (May 15, 2018) (explaining that lack of transparency hampers 340B payment accuracy and that "methods that operate at the claim level can improve accuracy in identifying 340B claims and thereby help prevent duplicate discounts and improve collection of rebates").

[5] States provide Medicaid services through either fee-for-service or managed care. Under fee-for-service, States reimburse providers directly for each service delivered. Under managed care, States typically contract with managed care plans to provide a specific set of services to Medicaid beneficiaries (which could include drugs) and prospectively pays each plan a set amount per beneficiary per month to provide or arrange those services. The Medicaid Drug Rebate Program had historically been limited to drugs provided under fee-for-service, but in 2010, the Patient Protection and Affordable Care Act expanded the Program by also requiring drug manufacturers to provide rebates for drugs provided under managed care. *See* Pub. L. No. 111-148, § 2501(c), 124 Stat. 119, 308 (2010) (codified at 42 U.S.C. §§ 1396b(m)(2)(A)(xiii), 1396r-8(b)(1)).

[6] Covered entities contract with pharmacies to dispense 340B drugs to the covered entities' patients. Before 2010, HRSA permitted covered entities to designate only one contract pharmacy for dispensing 340B drugs. In 2010, HRSA changed that policy and permitted covered entities to contract with an unlimited number of pharmacies, but failed to impose meaningful limitations or safeguards. *See* 75 Fed. Reg. 10,272 (Mar. 5, 2010).

"HRSA does not assess whether covered entities are actually following state policies and procedures regarding the use and identification of 340B drugs for Medicaid beneficiaries," which is "inconsistent with federal standards for internal control." *Id.* at 24. Consequently, "HRSA's audits do not provide the agency with reasonable assurance that covered entities are taking the necessary steps to prevent duplicate discounts," and "manufacturers are at risk of being required to erroneously provide duplicate discounts for Medicaid drugs." *Id.* at 25.

~~48.~~58. In addition, "HRSA audits do not assess for the potential for duplicate discounts in Medicaid managed care," *id.*—even though "the majority of Medicaid enrollees, prescriptions, and spending for drugs are in managed care, and the drug manufacturers [GAO] contacted believe that duplicate discounts are more prevalent in Medicaid managed care than [fee-for-service]." *Id.* at 26; *see also id.* at 6 & n.14 (noting that in fiscal year 2018, "71 percent of Medicaid drug prescriptions were in managed care"). Ten years after Congress expanded the Medicaid Drug Rebate Program to include managed care, "HRSA still has not issued guidance on how covered entities should prevent duplicate discounts in Medicaid managed care and has indicated that it is not pursuing new guidance at this time." *Id.* at 30.[7] This inaction, GAO observed, "is contrary to federal law," *id.* at

[7] In 1993, to comply with the statutory mandate to "establish a mechanism to ensure that covered entities comply" with the prohibition on duplicate discounts, 42 U.S.C. § 256b(a)(5)(~~a~~A)(ii), HRSA required covered entities that provide 340B drugs to Medicaid patients to provide the agency with the provider numbers they use to bill the State for those drugs. *See* 58 Fed. Reg. 27,293 (May 7, 1993). That information should be included in a "Medicaid Exclusion File," which States can use to identify 340B drugs. *See* January 2020 GAO Report at 11. But this file does not capture covered entities' provision of 340B drugs in the Medicaid managed care context, and HRSA still "has not created a mechanism for covered entities to use to identify 340B drugs provided to Medicaid managed care beneficiaries." *Id*. While HRSA has "recognize[d] the need to address covered entities' role in preventing duplicate discounts under Medicaid managed care," HRSA, Rel. No. 2014-1, *Clarification on Use of the Medicaid Exclusion File* at 3 (Dec. 12, 2014), it has cited its own lack of guidance as the basis for "not requiring covered entities to address identified duplicate discounts related to Medicaid managed care." January 2020 GAO Report at 26.

26, and "continues to leave the 340B Program vulnerable" to duplicate discounts, *id.* at 30; *see also* 2018 GAO Report at 40 ("Until HRSA develops guidance and includes an assessment of the potential for duplicate discounts in Medicaid managed care as part of its audits, the agency does not have assurance that covered entities' efforts are effectively preventing noncompliance.").

~~49.~~59. "[M]anufacturers lack complete information on the extent to which covered entities use 340B drugs for Medicaid beneficiaries" because HRSA does not collect "information on whether covered entities are using 340B drugs for Medicaid managed care beneficiaries," and the data it does collect may not include "information on contract pharmacies that are dispensing these drugs to Medicaid beneficiaries on covered entities' behalf." January 2020 GAO Report at 32.

~~50.~~60. Moreover, although "drug manufacturers can request approval from HRSA to audit a covered entity to investigate suspicions of duplicate discounts," ~~they~~the manufacturers must first "document reasonable cause." *Id.* at 34. And because "HRSA requires the drug manufacturer to use an independent auditor who follows government auditing standards," the "cost of audits may outweigh the benefits received in the form of repayments." *Id.* Manufacturers that have pursued audits have found the process to be burdensome and ineffective, with HRSA failing to intervene and require covered entities to return improper discounts ~~not properly requested~~. Indeed, in the managed care context, "HRSA does not require covered entities to repay manufacturers for duplicate discounts." *Id.*

~~51.~~61. The result is a broken system in which HRSA has been either unwilling or unable effectively to ensure compliance with statutory requirements and prevent duplicate discounts.

~~52.~~62. Even with its readily apparent failings, HRSA's program audits for fiscal years 2012–2019, as reported by GAO, found more than 400 duplicate discount violations. *See* December 2020 GAO Report at 14. Kalderos's own analysis confirms the extensive nature of the problem.

Kalderos confirmed duplicate discounts exceeding $23 million in 2019, up from the $17 million it documented in 2017. Based on its extrapolation of these findings, Kalderos estimates that in 2019 manufacturers, as a whole, paid a total of more than $1.2 *billion* in duplicate discounts.

~~53.~~63. Diversion, too, is a significant concern. HRSA's audits indicate that the problem is extensive. HRSA's 1,240 audits for fiscal years 2012–2019 documented more than 450 instances of diversion, plus an additional 83 findings related to inadequacies in covered entities' efforts to prevent diversion. *See* December 2020 GAO Report at 14. As with duplicate discounts, the diversion issue has been exacerbated by the rise in the use of contract pharmacies to dispense 340B drugs on covered entities' behalf. *See* 2018 GAO Report at 44 (reporting that 66 percent of the diversion findings in HRSA's audits "involved drugs distributed at contract pharmacies"); GAO, *Drug Discount Program: Status of GAO Recommendations to Improve 340B Drug Pricing Program Oversight* at 9 (Mar. 2015) (explaining that "increased use of the 340B Program by contract pharmacies and hospitals may have resulted in a greater risk of drug diversion to ineligible patients, in part because these facilities were more likely to serve patients that did not meet the definition of a patient of the program").[8]

~~54.~~64. 340B covered entities also have their concerns. Some have expressed the view that they are not always receiving the statutory ceiling price for covered outpatient drugs.

~~55.~~65. Some covered entities have also stated their belief that (1) States have not acted on information that covered entities have supplied to them and (2) despite access to data indicating that a 340B price has already been claimed on that utilization, States have claimed a duplicate

[8] As indicated previously, Kalderos takes no position as to whether contract pharmacy transactions are contrary to the 340B statute. That issue is being litigated elsewhere by other parties. *See supra*, n.1. ~~Kalderos's solution will permit contract pharmacy transactions to be honored, subject only to reasonable conditions that permit an effective means to address duplicate discounts and diversion.~~

Medicaid rebate. Covered entities complain that this creates the risk that they will be forced to return a 340B price that they have previously received, or at the very least, will be embroiled in a long, burdensome duplicate discount dispute.

~~56.~~66. Some covered entities have expressed frustration that HRSA has failed to develop and implement a specific means to identify 340B utilization that relates to a Medicaid managed care beneficiary. Covered entities have stated that they have been unnecessarily involved in duplicate discount disputes that are a function of inadequate Medicaid systems.

D. Kalderos's Solution

~~57.~~67. Kalderos understands the immense complexities and issues plaguing the 340B ~~Pro-gram~~program. Kalderos is not on any stakeholders' "side," but rather is committed to being an evenhanded broker administering a fair and efficient process that helps all stakeholders participate in this important program. Accordingly, Kalderos has invested significantly in technology designed to work with the 340B systems and the processes of covered entities.

~~58.~~68. In 2016, Kalderos concluded that a principal problem causing the breakdown in the 340B Program, from both a covered entity and a manufacturer perspective, was a failure to communicate essential information among covered entities, state Medicaid agencies, and manufacturers. Kalderos designed solutions to address this information gap and to facilitate efficient and compliant drug transactions effectuating the 340B ceiling price.

~~59.~~69. In particular, Kalderos created a multi-sided platform, *i.e.*, a platform that connects two or more interdependent user groups. The system is capable of multiple configurations. These systems are well known and widely used in other contexts. For example, two commonly recognized multi-sided platforms are the Uber and Lyft applications, which, at any given moment in any given city, connect hundreds or thousands of willing drivers to as many potential passengers. These

applications close the information gap between drivers and passengers and assist them in arranging and completing the transaction. Kalderos's solution similarly is designed to connect 340B providers to manufacturers selling drugs through the 340B ~~Program~~program to efficiently facilitate 340B transactions in a compliant manner, ensuring that both sides can have confidence in the transactions.

~~60.~~70. Kalderos's solution works as follows. A manufacturer involved with the 340B Program ~~subscribes to and~~ contracts with Kalderos to facilitate 340B transactions. The manufacturer then informs covered entities that they will need to use ~~Kalderos's~~the Kalderos platform to obtain 340B prices from that manufacturer ~~for contract pharmacy transactions~~.

~~61.~~71. Covered entities (or their 340B third-party administrators or vendors) review and accept Kalderos's terms and conditions for service to utilize the platform in connection with purchases of ~~that manufacturer's~~drug manufacturers' drugs under the 340B Program. The terms and conditions are intended to be similar to—or even easier to meet than—those that apply under traditional enrollment with a wholesaler by a covered entity, where the wholesaler submits 340B discount chargebacks to a manufacturer on behalf of a 340B covered entity.

~~62.~~72. Among these terms and conditions is a requirement that covered entities~~,~~ (or their 340B third-party administrators or vendors), when submitting a request for 340B prices, provide certain minimal claims information. That claims information includes the Rx number, prescriber identification number, national drug code, number of units, date of service, and 340B covered entity identification number. This small set of data points is sufficient to enable Kalderos to address duplicate discounts and diversion issues.

~~63.~~73. Information like this is routinely required by manufacturers that offer price concessions to a broad range of non-340B customers, including managed care companies, hospitals,

physician practices, retail pharmacies, group purchasing organizations, and even States participating in the Medicaid program. *See e.g.*, MDRP Electronic State Invoice Form CMS-R-144, Data Definitions (effective July 1, 2021), https://www.medicaid.gov/medicaid/prescription-drugs/downloads/cms-r-144-state-invoice-data-definitions-jul-2021.pdf (addressing the regular practice of state Medicaid programs to request rebates by providing record ID, labeler code, units reimbursed, package size, number of prescriptions, and other data in their pricing invoices to manufacturers); HHS Office for Civil Rights, HIPAA FAQ 455, https://www.hhs.gov/guidance/document/faq-455-does-privacy-rule-permit-health-plans-disclose-protected-health-information (addressing "health plans disclos[ing] protected health information, such as prescription numbers, to a pharmaceutical manufacturer" for purposes of "adjudicating claims submitted under a drug rebate contract"); Mark Campbell, RxBenefits, *What Employers Need to Know about Drug Rebates* (June 24, 2021), https://www.rxbenefits.com/blogs/understanding-the-role-of-drug-rebates/ (drug price concessions "are paid on a per claim basis"); National Council for Prescription Drug Plans, Manufacturer Rebate Flat File Implementation Guide, Version 07 (Jan. 24, 2018), at 15, 20–22 (standard setting organization "flat file" used by "State Medicaid Agencies, Health Maintenance Organizations ~~…,~~ . . . , Pharmacy Benefit Managers ~~…,~~ . . . , Long Term Care Facilities, Mail Order Providers, Insurance Carriers, Employer Groups, etc." to seek drug price concessions includes such standard data elements as "Claim Number", "Prescriber ID", "Prescription/Service Reference Number"); *see also* 63 Fed. Reg. ~~35,239,~~at 35,241 ~~(June 29, 1998)~~ (HRSA itself encouraging state AIDS Drug Assistance Programs to make "detailed and accurate" "claim data" available to manufacturers).

~~64.~~74. After the parties are set up on ~~Kalderos's~~the Kalderos platform, the covered entity (and/or its third-party administrator or vendor) assesses the ~~contract pharmacy~~ transaction. If it

believes it is appropriate to submit the transaction for 340B pricing, it supplies the claim information to Kalderos. Kalderos uses the prescription information provided by the covered entity to determine if a Medicaid rebate already has been provided for the drug being dispensed~~.~~, which would be unlikely given the lagged timing of Medicaid rebate invoices. If no duplicate discount is present at the time the covered entity submits the 340B price request ~~and no diversion issue is identified~~, Kalderos informs the manufacturer, which then reviews Kalderos's recommendation and agrees to provide 340B pricing. Kalderos then notifies the covered entity that the transaction qualifies for 340B pricing and provides instructions to the manufacturer's bank to remit payment ~~remittance.~~through a direct cash rebate to the covered entity within days of the covered entity's request. This is all done electronically and the covered entity has real-time, around-the-clock visibility into the transaction's status. If a Medicaid rebate, a price or a rebate under the IRA, or other 340B discount is subsequently requested on that same utilization, the manufacturer can dispute that discount or rebate request without involving the covered entity, relieving covered entities of the burden and cost of becoming involved in such disputes.

~~65.~~75. In this way, Kalderos facilitates the provision of the statutory ceiling price for covered entities, while at the same time addressing circumstances where discounts or rebates on the same drug dispensed by the covered entity are or will be claimed. In an effort to head off duplicate discounts before they even are sought, Kalderos creates a ledger of the transactions for which 340B prices have been paid ~~and uses that~~. The ledger is used to cross-check against the quarterly Medicaid file to ensure no duplicate Medicaid rebates will be paid. This mechanism addresses the federal regulators' failure to design a system to address duplicate Medicaid managed care rebates. Likewise, the prescription identification number can be used to identify prescriptions purchased by group purchasing organizations from which some classes of covered entities cannot purchase

340B drugs or to identify prescribers that are not affiliated in any way with a covered entity. The claims information Kalderos collects is essential to performing these functions. Without it, Kalderos could not identify and prevent duplicate discounts and instances of diversion, leaving the 340B ~~Program~~program broken.

~~66. In order to tailor the scope of its solution, Kalderos requires claims information to be provided only for contract pharmacy transactions—focusing on a specific area that GAO and other governmental entities have acknowledged are a particular source of concern. *See, e.g.*, GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* at 28 (Sept. 2011) ("Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."); 2018 GAO Report at 44 (reporting that approximately two-thirds of diversion findings in HRSA audits involved drugs distributed at contract pharmacies, and concluding that "noncompliance at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices"); *see also* OIG, *Testimony Before the U.S. Senate Committee on Health, Education, Labor, and Pensions* at 5 (May 15, 2018) (stating that OIG "has identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements").~~

~~67.~~76. The information requested by Kalderos is not burdensome for covered entities to provide. It is readily available information and matches what covered entities and their third-party administrators typically include when they attempt to "match" a drug dispensed to a 340B patient. It is also the very same information customarily provided in the pharmacy or healthcare claim submitted by the 340B covered entity to secure reimbursement for the drugs from a third-party payor, like the Medicaid or Medicare programs. *Cf. Novartis*, 102 F.4th at 463 (noting that "the burden of providing the claims data is 'minimal'"). The information requested by Kalderos also is

customary when managed care entities, hospitals, physicians, retail pharmacies, group purchasing organizations, and States participating in the Medicaid program seek non-340B price concessions pursuant to price concession agreements with manufacturers or other pricing programs. In other words, when providing price concessions, manufacturers routinely seek the information necessary to confirm that program requirements for those price concessions are met. If 340B covered entities were permitted to refuse to provide such basic information, they would enjoy a preference over all other purchasers receiving price concessions. The statute does not require such a preference.

77. But Kalderos's solution also benefits 340B covered entities. In developing its solution, Kalderos worked closely with covered entities to identify the transaction points in the traditional system that created the greatest risk of a noncompliant transaction and to ensure that feedback provided by covered entities was integrated.[9] The result is a solution that reduces burdens on covered entities through direct payments and a simple, intuitive, and easy-to-use platform. ~~In fact, because Kalderos's~~

~~68.~~78. In particular, covered entities will be able to request 340B pricing immediately after a drug dispense to a patient and be paid weekly, often before payment is required by a wholesaler and without needing to accumulate dispenses to a package size, which is necessary under the current practice. As such, covered entities will typically realize the 340B price faster than they do today. Further, because the Kalderos platform works directly with 340B covered entities and Medicaid rebates are requested on a time-lagged basis, often months in arrears, Kalderos's solution will allow 340B ~~covered~~ entities to routinely assert, receive, and validate their price concessions

[9] In addition to working with covered entities and manufacturers, since inception, Kalderos has steadily built relationships with state Medicaid agencies, and now has relationships with Medicaid agencies in 49 States and the District of Columbia. Kalderos collaborates with state Medicaid agencies to identify and correct misapplied and duplicate discounts between 340B and Medicaid.

before a duplicate discount can arise. The need for a solution for the problem of duplicate discounts and rebates is even greater now in light of the discounts and rebates required under the IRA. Manufacturer disputes that arise thereafter will then, in the normal course, be focused on the ~~States~~Medicaid or Medicare programs, not the 340B covered entities.

E. HRSA's ~~New~~ Policy Prohibiting All Conditions on Manufacturer Offers

~~69.~~79. Beginning in mid-2020, some drug manufacturers began imposing conditions on their offers to sell 340B drugs to covered entities at the statutory ceiling price. Among other conditions, several manufacturers required covered entities dispensing 340B drugs through contract pharmacies to provide claims data to third-party platforms.

~~70.~~80. On December 30, 2020, the General Counsel of HHS issued an Advisory Opinion on contract pharmacy arrangements under the 340B ~~Program~~program. *See* HHS, *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* (Dec. 30, 2020). The Advisory Opinion focuses on the government's view that contract pharmacy arrangements must be honored under the statute, but it also states the following:

> In responding to a comment regarding perceived 340B violations, HRSA stated "[m]anufacturers cannot condition sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity." *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 82 Fed. Reg. 1210, 1223 (Jan. 5, 2017).

~~71.~~81. As noted above, a number of manufacturers filed suit arguing, in part, that the Advisory Opinion was unlawful. In the lawsuit brought by AstraZeneca, Judge Stark issued an Order on June 16, 2021 that, in part, rejects the governments arguments that "the Opinion merely restates a position that the government has held throughout the entirety of the 340B Program." *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. ~~No. 1:21-cv-27, 2021 WL 2458063~~3d 47, at ~~*5~~54–55 (D.

Del. ~~June 16,~~ 2021). Judge Stark further stated that he found that "the Opinion is legally flawed." *Id*. at ~~*8~~59.

~~72.~~82. Two days after Judge Stark's Order, HHS withdrew the Advisory Opinion, purportedly "in light of ongoing confusion about the scope and impact of the Opinion." *See* HHS, *Notice of Withdrawal* (June 18, 2021). However, it is clear that the withdrawal did not reflect any change in HRSA policy. In the Notice, HHS stated that the "withdrawal of the Opinion does not impact the ongoing efforts of the Health Resources and Services Administration (HRSA) to enforce the obligations that 42 U.S.C. § 256b places on drug manufacturers." *Id.* Despite its withdrawal in the face of Judge Stark's criticism, the policies announced in the Advisory Opinion for the program as a whole continue to be HRSA's policy and its positions represent final agency action.

~~73.~~83. On May 17, 2021, ~~Defendant~~ Diana Espinosa, in her official capacity as Acting Administrator of HRSA, sent letters to various drug manufacturers declaring all conditions placed by manufacturers on their offers of 340B pricing unlawful. Three letters, in particular, were addressed to manufacturers United Therapeutics, Sanofi, and Novartis, which had required covered entities dispensing 340B drugs though contract pharmacies to provide claims data as a condition of obtaining 340B pricing. As of this filing, the letters were posted on HRSA's website at https://www.hrsa.gov/opa/program-integrity/index.html.[~~10~~] Although the letters are styled as statements to individual manufacturers, they are clearly policy statements that universally purport to prohibit any conditions of any kind, without regard to any individual fact or circumstance.

84. The substance of these three letters is identical. Each letter—without discussing or even citing HRSA's 1994 Guidance on manufacturer conditions—announced a new policy

[~~10~~] ~~The letters are also attached as Exhibits A, B, & C to this Complaint.~~

declaring unlawful *all* conditions placed by manufacturers on their offers to sell 340B drugs at the statutory ceiling price, including conditions requiring the production of claims data~~:~~.

~~74.~~85. Further, the body of one of the letters is reproduced below, in relevant part, with emphasis added:

> The Health Resources and Services Administration (HRSA) has completed its review of United Therapeutics Corporation's (United Therapeutics) policy that places restrictions on 340B pricing to covered entities that dispense medication through pharmacies, unless the covered entities provide claims data to a third-party platform. After review of this policy and an analysis of the complaints HRSA has received from covered entities, HRSA has determined that United Therapeutics' actions have resulted in overcharges and are in direct violation of the 340B statute.
>
> Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers "shall…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." This requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. **Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities. Furthermore, the 340B statute does not permit manufacturers to impose conditions on covered entities' access to 340B pricing, including the production of claims data**.

~~75.~~86. In the wake of the May 17 letters, the manufacturers who received them each filed suit, challenging the agency's determination that manufacturers must provide 340B pricing on drugs dispensed through contract pharmacies. *See supra*, n.1. United Therapeutics and Sanofi also challenged the agency's determination that manufacturers may not condition 340B prices on covered entities' production of claims data. *See United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-01686-DLF (D.D.C. June 23, 2021); *Sanofi-Aventis U.S., LLC v. ~~U.S. Dep't of Health & Hum. Servs.~~,HHS,* No. 3:21-cv-00634-FLW (D.N.J. Jan. 12, 2021). This action challenges only the latter determination; Kalderos takes no position on the contract pharmacy issue in this action.

~~76.~~87. On September 22, 2021, HRSA sent additional letters to manufacturers, including United Therapeutics, Sanofi, and Novartis, that reinforced the final nature of its unqualified policy

pronouncements in the May 17, 2021 correspondence. Specifically, the matters discussed in the May 17, 2021 correspondence were referred to the OIG for enforcement, indicating that HRSA would not be rescinding its prior policy statements.

~~77.~~88. ~~Then, finally, just a few days ago, on~~On October 4, 2021, HRSA sent another "violation" letter to another manufacturer. This ~~most~~more recent letter, indistinguishable from the May 17 letters cited above, also included the same broad, blanket policy declaration that "[n]othing in the 340B statute grants a manufacturer the right to place conditions" on covered entities 340B purchases. ~~As of this filing, the letter is posted on HRSA's website at https://www.hrsa.gov/opa/program-integrity/index.html. With HRSA having stated and restated its novel "no conditions" policy recently, multiple times, Kalderos has no choice but to bring this action.~~

F. Federal Appellate Decisions Striking Down HRSA's Policy

89. On May 21, 2024, the D.C. Circuit ruled that Defendants could not "categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities." *Novartis*, 102 F.4th at 464. The *Novartis* Court went on to hold that the disputed manufacturer conditions—including claims-data requirements—"do not violate section 340B on their face." *Id.*

90. Similarly, the Third Circuit in the *Sanofi* case also held that HRSA "overstepped the statute's bounds" by concluding that the 340B statute prevented manufacturers from imposing any conditions on their offer of outpatient drugs to covered entities under the 340B program. *Sanofi v. HHS*, 58 F.4th 696, 707 (3d Cir. 2023). Like the D.C. Circuit, the Third Circuit ruled that the conditions adopted by the drug manufacturers in that case were "lawful." *Id.* at 704.

91. Defendants did not seek en banc reconsideration or petition for certiorari from the decisions in *Novartis* or in *Sanofi*.

G. Further Communications with HRSA About the Kalderos Platform

92. On August 7, 2024, Kalderos entered into an agreement with Eli Lilly & Company ("Lilly") through which Lilly would use the Kalderos platform to satisfy its obligations under the 340B statute.

93. On August 9, 2024, Kalderos communicated with HRSA concerning its platform, which requires covered entities to provide limited claims data and effectuates the 340B price through a direct cash rebate to covered entities. Email from Kalderos to HRSA (Aug. 9, 2024). Kalderos explained that its platform was to be launched with a manufacturer in the coming months. *Id.*

94. Kalderos made clear that, under its platform, claims-level data are exchanged between all parties, ensuring accurate and timely payment of discounts and preventing nearly 100% of non-compliant discounts. Kalderos further showed that its model builds in compliance checks that ensure that a covered entity is approved for 340B pricing and that duplicate discounts across all discount programs can be avoided. *Id.*

95. Kalderos also explained that developments relating to the Inflation Reduction Act ("IRA") and the 340B Alternative Dispute Resolution ("ADR") process "necessitate a transition to a 340B rebate model." *Id.* In addition, Kalderos highlighted that CMS has recognized in IRA guidance that a rebate model is necessary and appropriate to implement the Maximum Fair Price while complying with the duplicate discount prohibitions built into the statute. *Id.* Kalderos pointed out that the new ADR regulations require manufacturers to obtain relevant information to support or defend an ADR claim, and that Kalderos's rebate model allows for the identification of that

necessary information in an efficient manner that minimizes the requests made of covered entities or others. *Id.*

96. On September 4, 2024, Kalderos and Lilly presented the Kalderos platform to HRSA. They explained that the Kalderos platform was needed to comply with the 340B statute's prohibition against duplicate discounts and rebates and to implement the IRA. And they highlighted that the Kalderos platform was necessary to allow manufacturers to obtain data necessary to initiate or defend against ADR proceedings under the 340B statute.

97. Kalderos and Lilly underscored that the Kalderos platform was better for all stakeholders for multiple reasons. Under the platform, Lilly would issue rebates weekly, so covered entities would receive cash rebates directly within days of dispensing the 340B products. Under the existing replenishment model, dispensed products are acquired at the market price and are restocked with 340B priced replenishments, thereby requiring covered entities to wait until an entire product package is dispensed before they can obtain a replenishment product at the 340B price.

98. Under the Kalderos platform, moreover, the manufacturer and covered entity would have equal access to the same claims data thereby making the system more transparent and facilitating the identification of duplicate discounts and possible diversion. Kalderos and Lilly explained that the proposed effective date for implementing the Kalderos Platform would be November 1, 2024.

99. After the meeting on September 4, 2024, HRSA sent an email to Kalderos acknowledging the meeting to discuss "Kalderos' Direct Discount Platform--which would effectuate the 340B price directly to a covered entity as a rebate." E-mail from HRSA to Kalderos (Sept. 4, 2024). HRSA then stated that "[u]nder the 340B Program, the Pharmaceutical Pricing Agreement (PPA)

is between the Secretary of HHS and the manufacturer" and "[t]o the extent a manufacturer would like to discuss its model for 340B pricing with HRSA, HRSA would engage with the manufacturer directly as it is a party to the PPA and responsible for compliance under the 340B Program." *Id.*

100. On September 5, 2024, Kalderos (i) thanked HRSA for "meeting with Kalderos and Lilly yesterday to discuss Kalderos' Direct Discount Platform," (ii) highlighted that the September 4th discussions "are just the most recent of many communications between Kalderos and the HRSA team, dating back to 2019, about Kalderos' Platform," and (iii) assured HRSA that the Kalderos platform continues to be a means "for ensuring the proper operation of the 340B Program for covered entities and manufacturers alike." E-mail from Kalderos to HRSA (Sept. 5, 2024).

101. On September 9, 2024, Lilly sent a follow-up letter to HRSA explaining its intention to satisfy its 340B obligation to provide a ceiling price through a rebate via a cash replenishment program, specifically using Kalderos' Truzo™ platform." Letter from Eli Lilly to HRSA (Sept. 9, 2024). Lilly expressed its hope that HRSA would "issue a statement endorsing Lilly's efforts to advance the cause of 340B--and broader government healthcare--program integrity." *Id.* at 1. Lilly highlighted that the "340B statute clearly states that rebates are a permissible form for offering and effectuating a 340B ceiling price." *Id.* at 3 (citing 42 U.S.C. § 256b(a)(1)). That is, "as a matter of law, the statutory requirement to offer covered entities covered outpatient drugs at the ceiling price can be effectuated either with an upfront discount or a post-purchase rebate." *Id.*

102. On September 18, 2024, HRSA sent Lilly a letter stating that implementation of the Kalderos platform would violate the 340B statute. *See* September 18 Decision at 1. HRSA stated that "the Secretary has not provided for such rebate as proposed by Lilly" and "[t]herefore, implementing such a proposal at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval of a rebate model such as Lilly has proposed." *Id.*

103. On September 23, 2024, Lilly conveyed its disappointment concerning HRSA's rejection of "Lilly's cash replenishment model and [HRSA's] determination that implementing a rebate model without affirmative approval would violate the 340B statute." Letter from Eli Lilly to HRSA (Sept. 23, 2024).[11] The letter further requested that HRSA inform Lilly by October 7th whether it had changed its position that the Kalderos platform was unlawful. *Id.* at 7. HRSA did not do so.

104. At the same time, on September 17, 2024, HRSA (i) informed another manufacturer that the 340B statute requires preapproval of a rebate before it can be implemented under the 340B program, and (ii) threatened that adoption of the rebate model would subject the manufacturer to cancelation of its Pharmaceutical Pricing Agreement and civil monetary penalties. Letter from HRSA to Johnson & Johnson at 2 (Sept. 17, 2024) ("September 17th Decision").[12]

ARTICLE III STANDING

~~78.~~105. Kalderos has Article III standing to bring this lawsuit ~~because~~. HRSA's ~~new~~ policy prohibiting ~~manufacturer conditions, including conditions~~ manufacturers from requiring the production of claims data, ~~causes~~and its September 18 Decision cause Kalderos injury-in-fact, and a favorable decision by this Court would redress that injury.

106. HRSA's ~~new~~ policy ~~injures~~and September 18 Decision directly injure Kalderos ~~by substantially reducing~~. Kalderos has entered into one or more agreements with drug manufacturers to implement their obligations under the ~~demand for its services.~~340B program. Under the agreements, Kalderos obtains compensation if its 340B platform is being used by drug manufacturers

[11] Lilly also provided responses to a series of questions posed by HRSA in its September 18, 2024 Letter. *Id.* at 1–7.

[12] On September 27, 2024, HRSA reiterated that "the 340B statute requires Secretarial approval of any rebate mechanism." Letter from HRSA to Johnson & Johnson at 1 (Sept. 27, 2024).

that contract with Kalderos. HRSA's policy and September 18 Decision injure Kalderos by declaring that its platform is inconsistent with the 340B statute.

~~79.~~107. To the extent that the agency prohibits manufacturers from requiring the collection of claims data, that determination causes injury to Kalderos. Without the claims data Kalderos collects from covered entities, ~~Kalderos's solution~~the Kalderos platform cannot function. Consequently, if manufacturers cannot require covered entities to produce claims data, few, if any, manufacturers will contract or persist in a contractual arrangement with Kalderos. ~~Although two~~Likewise, if manufacturers ~~have signed up with Kalderos, other~~are not permitted to offer the 340B pricing through a direct rebate to covered entities, then few if any manufacturers ~~have informed Kalderos that they~~ will ~~retain~~contract with Kalderos ~~if and only if HRSA's new policy is set aside.~~for use of its platform.

~~80.~~108. This economic injury to Kalderos's business—caused by regulatory action that reduces the demand for Kalderos's solution and redressable by a decision from this Court setting aside that regulatory action—constitutes injury-in-fact under Article III. *See, e.g.*, *Clinton v. City of New York*, 524 U.S. 417, 432–33 (1998); *Am. Fuel & Petrochemical Mfrs. v. EPA*, 3 F.4th 373, 379–80 (D.C. Cir. 2021); *Airlines for Am. v. TSA*, 780 F.3d 409, 410–11 (D.C. Cir. 2015); *Energy & Env't Legal Inst. v. Epel*, 793 F.3d 1169, 1175 n.1 (10th Cir. 2015) (Gorsuch, J~~.)~~.); *Energy Future Coal. v. EPA*, 793 F.3d 141, 144–45 (D.C. Cir. 2015).[13]

[13] *Id.* ("The standing question in this case is straightforward: If the Government prohibits or impedes Company A from using Company B's product, does Company B have standing to sue? Suppose the FDA bans or makes it harder for soda manufacturers to use sugar. Does a sugar manufacturer have standing to sue? Or suppose the District of Columbia bans or makes it harder for concession stands to sell hot dogs. Does a local hot dog manufacturer have standing to sue? Ordinarily the answer to those questions is yes. In such cases, both Company A and Company B are 'an object of the action (or forgone action) at issue,' so 'there is ordinarily little question' that they have standing . . . .").

FINAL AGENCY ACTION

~~81.~~109. HRSA's policy prohibiting manufacturer conditions, first announced in its May 17, 2021 letters, is final agency action because it "mark[s] the 'consummation' of the agency's decisionmaking process" and is an action "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); *see Pharm. Rsch. & Mfrs. of Am. v. HHS*, 138 F. Supp. 3d 31, 39–47 (D.D.C. 2015). It is clear from the Advisory Opinion, the May 17 letters and their broad prohibition against the use of any conditions, and the referral to OIG, that HRSA has finally determined that, in its words, the 340B statute does "not permit manufacturers to impose conditions" of any kind, no matter how reasonable.

110. Likewise, HRSA's September 18 Decision is final agency action, which marks the consummation of the agency's decisionmaking process and determines legal rights. Although the September 18 Decision was issued to Lilly, Defendants were aware that Kalderos has contracted with Lilly to provide the use of its platform. HRSA's September 18 Decision directed to Lilly thus reflects HRSA's determination about the legality of the Kalderos platform under the 340B statute. Indeed, despite years of interactions between HRSA and Kalderos, on September 4, 2024, HRSA informed Kalderos that it would no longer deal directly with Kalderos, but instead would deal only with manufacturers that had entered into the PPA with the Secretary.

COUNT I: AGENCY ACTION IN EXCESS OF STATUTORY AUTHORITY
(5 U.S.C. § 706; 42 U.S.C. § 256b) (Prohibition of Claims Data)

~~82.~~111. Each of the foregoing paragraphs is incorporated by reference.

~~83.~~112. HRSA's ~~new~~ policy prohibiting manufacturers from ~~placing any conditions including~~ requiring production of basic claims data ~~on their offers to sell drugs to covered~~

~~entities at the statutory ceiling price~~ exceeds the scope of HRSA's statutory authority under Section 340B as the D.C. Circuit's analysis in *Novartis* makes clear.

~~84.~~113. Section 340B imposes only one requirement on drug manufacturers' offers to sell 340B drugs~~— manufacturers~~: Manufacturers must "offer each covered entity covered outpatient drugs for purchase at or below the applicable [statutory] ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). Kalderos's solution ensures that manufacturers offer 340B pricing when required under the statute. The statute precludes an entity from claiming covered entity status when duplicate discounts or diversion is present. *See id.* at § 256b(a)(4) ("[T]he term covered entity means an entity that meets the requirements described in paragraph (5)," which includes both duplicate discount prohibition and the diversion prohibition). HRSA has no authority to require the statutory ceiling price to be offered when the covered entity is not entitled to it.

~~85.~~114. Apart from imposing a statutory ceiling price, the text of Section 340B imposes no other requirements with regard to the terms and conditions on which drug manufacturers participating in the 340B Program may offer to sell covered outpatient drugs to covered entities. In particular, Section 340B does not prohibit drug manufacturers from requiring covered entities to provide claims data—e.g., the Rx number—as a condition of the manufacturers' offer to sell covered outpatient drugs at the statutory ceiling price.

~~86.~~115. At a minimum, Section 340B does not prohibit manufacturers from requiring covered entities to provide basic claims data where, as here, that information can be used to determine whether the transaction is consistent with the statutory purposes to prevent duplicate discounts and diversion and does not impede covered entities' ability to access covered outpatient drugs at the statutory ceiling price, when they are, in fact, entitled to 340B pricing. 340B pricing

is not owed where a duplicate discount or diversion is present. *See id*. § 256b(a)(4~~) and~~), (5). By statute, compliance with these prohibitions is required to entitle 340B covered entities to the ceiling price. *Id.*

~~87.~~116. HRSA's contrary reading of the statute reflected in its May 2021 letters conflicts with the statute's unambiguous terms and is arbitrary and capricious.

~~88.~~117. To the extent HRSA's ~~new~~ policy rests on an assertion of authority to impose additional requirements over and above the statutory ceiling price required by Congress, this policy exceeds the agency's statutory authority. Apart from ~~imposing~~insisting upon a statutory ceiling price, Congress left it to the parties to address the terms and conditions of 340B sales. Accordingly, there is no "gap" in the statute for HRSA to fill, under the guise of "interpretation" or otherwise.

~~89.~~118. In any event, as this ~~Court~~court has ~~held~~determined, HRSA also has no general "gap filling" authority to impose requirements that go beyond those set forth in the statute and PPA. *See Pharm. Rsch. & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 37–45 (D.D.C. 2014) (holding that HRSA lacks general rulemaking authority ~~under the 340B Program).~~with regard to the 340B Program); *see also Novartis*, 102 F.4th at 456 ("The Secretary lacks rulemaking authority over the section 340B program"); *Sanofi*, 58 F.4th at 703 (same). As HRSA itself has recognized, it has no authority to enforce guidance "unless there is a clear violation of the 340B statute." Richard Church et al., K&L Gates LLP, *340B Update: HRSA Indicates it Lacks Authority to Enforce 340B Program Guidance* (July 23, 2020), ~~https://www.jdsupra.com/legalnews/340b-update-hrsa-indicates-it-lacks-69793/.~~https://www.jdsupra.com/legalnews/340b-update-hrsa-indicates-it-lacks-69793/.

~~90.~~119. HRSA's ~~new~~ policy is therefore unlawful because it is "not in accordance with law" and "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A), (C).

~~91.~~120. Kalderos lacks an adequate remedy at law for Defendants' unlawful action.

COUNT II: ARBITRARY AND CAPRICIOUS AGENCY ACTION
(5 U.S.C. § 706; 42 U.S.C. § 256b) (Prohibition of Claims Data)

~~92.~~121. Each of the foregoing paragraphs is incorporated by reference.

~~93.~~122. HRSA's ~~new~~ policy prohibiting manufacturers from ~~placing any conditions including~~ requiring production of basic claims data ~~on their offers to sell drugs to covered entities at the statutory ceiling price~~ is arbitrary and capricious.

~~94.~~123. HRSA's 1994 Guidance on manufacturer conditions does not prohibit manufacturer conditions in general or conditions requiring the production of claims data in particular. To the contrary, the agency's 1994 Guidance recognized that manufacturers are permitted to engage in "customary business practice[s], request standard information, [and] include other appropriate contract provisions" with regard to their 340B sales. 59 Fed. Reg. at 25,~~113~~114; *see also id.* at 25,111–12 (stating that manufacturers may not "single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective"). The May 17, 2021 letters do not even cite the 1994 Guidance, let alone explain how the agency's ~~new~~ policy can be reconciled with the 1994 Guidance or why the agency decided to depart from it. Nor do they address the other circumstances in which HRSA has permitted manufacturers to impose conditions on 340B sales to covered entities. HRSA's ~~new~~ policy is thus an unexplained and unreasonable departure from the 1994 Guidance and the agency's past and current practice.

~~95.~~124. HRSA also failed to provide a reasoned explanation for its ~~new~~ policy and to meaningfully grapple with significant aspects of the problem. HRSA did not explain how any

statutory objective would be undermined by requiring covered entities to produce claims data that can be used to detect and prevent duplicate discounts and diversion in violation of the statute. HRSA did not address the significant threat to the integrity of the 340B Program posed by duplicate discounts and diversion or the extent to which manufacturer conditions requiring production of claims data, such as Rx and prescriber identification numbers, could ameliorate that problem without impeding covered entities' ability to access 340B drugs at the statutory ceiling price. And HRSA did not explain why audits and administrative dispute resolution—after-the-fact mechanisms that to date have proven largely ineffective at ensuring compliance with statutory requirements—cannot be supplemented by prophylactic measures that help prevent duplicate discounts and diversion from occurring in the first place. Indeed, Kalderos was previously advised that HRSA had recommended to the Department that its model be acknowledged as entirely consistent with the 340B statute.

125. Claims data also are necessary to ensure compliance with the Inflation Reduction Act's requirements and to implement properly the 340B statute's ADR process. HRSA has arbitrarily and capriciously ignored these crucial considerations in opposing the claims-data requirement in the Kalderos platform.

~~96.~~126. HRSA's ~~new~~ policy is therefore unlawful because it is "arbitrary, capricious, [and] an abuse of discretion." 5 U.S.C. § 706(2)(A).

~~97.~~127. Kalderos lacks an adequate remedy at law for Defendants' unlawful action.

COUNT III: AGENCY ACTION IN EXCESS OF STATUTORY AUTHORITY (5 U.S.C. § 706; 42 U.S.C. § 256b) (Direct Rebates)

128. Each of the foregoing paragraphs is incorporated by reference.

129. HRSA's rejection of the Kalderos platform because it provides covered entities with the statutory ceiling price using a direct rebate is contrary to law.

130. In its September 18 Decision, HRSA imposed a preapproval requirement before a manufacturer may offer the ceiling price to covered entities through a rebate. *See* September 18 Decision at 1 ("To date, the Secretary has not provided for such rebate as proposed by Lilly. Therefore, implementing such a proposal at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval of a rebate model such as Lilly has proposed.").

131. Similarly, in a related determination posted by HRSA on its website, HRSA stated that a rebate cannot be "tak[e]n into account" in "the amount required to be paid" to manufacturers, unless it has received preapproval by the Secretary. September 17th Decision at 2. HRSA continued that such rebates "violat[e] Section 340B(a)(1) of the PHS Act" because they require covered entities to purchase covered drugs "at prices that exceed 'the maximum price[s] that covered entities may permissibly be required to pay." *Id*.

132. These decisions are beyond the Secretary's authority under the 340B statute. The Secretary has no statutory authority to impose a preapproval requirement that operates to prohibit rebates to covered entities from manufacturers to effectuate the statutory ceiling price under the 340B statute. The 340B statute does not authorize HRSA to impose a preapproval requirement, to categorically prohibit manufacturers from offering the statutory ceiling price through rebates, or to disregard direct rebates provided to covered entities when assessing whether the requirements of the 340B statute have been met.

133. Indeed, the agency's position appears to be a back-door effort to dictate conditions on a manufacturer's *bona fide* offer of the 340B price to covered entities through a direct cash rebate. Multiple recent appellate court decisions have rejected HRSA's attempt to prohibit such conditions, affirming that Congress intended to allow "private parties" to "act freely" with respect

to 340B delivery conditions. *See Novartis*, 102 F.4th at 460; *Sanofi*, 58 F.4th at 707. HRSA's misinterpretation of the 340B statute would circumvent these appellate decisions and use its purported authority to approve or disapprove of rebate/discount models to prevent manufacturers from imposing reasonable conditions on the *bona fide* offer of the 340B price.

134. HRSA's September 18 Decision is therefore unlawful because it is "not in accordance with law" and "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A), (C).

135. Kalderos lacks an adequate remedy at law for Defendants' unlawful action.

COUNT IV: ARBITRARY AND CAPRICIOUS AGENCY ACTION (5 U.S.C. § 706; 42 U.S.C. § 256b) (Direct Rebates)

136. Each of the foregoing paragraphs is incorporated by reference.

137. HRSA's rejection of the Kalderos platform because it provides direct rebates to covered entities rather than up-front discounts is arbitrary and capricious.

138. *First*, the September 18 Decision offered no reasoned explanation for concluding that the Kalderos platform violates the 340B statute. Instead, HRSA stated that "the Secretary has not provided for such rebate as proposed by Lilly." September 18 Decision at 1 (stating that the 340B program "require[s] the approval of a rebate model such as Lilly has proposed"). The agency's bald statement that it has not "provided for such rebate as proposed by Lilly" is not reasoned decisionmaking.

139. *Second*, the agency has not and cannot offer any reasoned explanation for rejecting the Kalderos platform. Under the Kalderos platform, covered entities pay a market price to purchase covered outpatient drugs and provide limited claims data relating to those purchases. Purchases of covered outpatient drugs that qualify for the 340B discount trigger a rebate payment from the manufacturer directly to the covered entity and that rebate is timely, efficient, and

transparent. In assessing whether the Kalderos platform complies with the 340B statute, it would be arbitrary and capricious for the Secretary to look solely to the initial market price paid for the covered outpatient drug while ignoring the direct rebate provided from the manufacturer to the covered entity designed that ensures that the covered entity pays no more than the ceiling price. The Secretary's refusal to recognize a direct rebate from the manufacturer to the covered entity when assessing whether the manufacturer has complied with the 340B statute is arbitrary and capricious decisionmaking.

140. *Third*, the agency has not and cannot provide any reasoned basis for rejecting the Kalderos platform and requiring preapproval when the agency has allowed covered entities to employ a replenishment model, which operates through an after-the-fact sale of replenishment product at the 340B price following the purchase of a covered drug product at market prices. The replenishment model is a rebate model effectuated through subsequent purchases of covered products at the 340B price. The agency did not require or provide preapproval of the replenishment model, even though it involves after-the-fact rebates.

141. *Fourth*, the agency has failed to consider how its rejection of the Kalderos platform affects the ability of manufacturers to comply with their obligations under the 340B statute and also the requirements of the Inflation Reduction Act. The Kalderos model provides a mechanism through which illegal duplicate discounts within the 340B program and the IRA can be identified, avoided, and remedied after the fact if necessary. Nevertheless, the agency has disregarded the benefits of the Kalderos platform when it rejected its implementation in the September 18 Decision.

142. HRSA's September 18 Decision is therefore unlawful because it is "arbitrary, capricious, [and] an abuse of discretion." 5 U.S.C. § 706(2)(A).

143. Kalderos lacks an adequate remedy at law for Defendants' unlawful action.

PRAYER FOR RELIEF

Kalderos respectfully requests that the Court enter judgment in its favor and grant the following relief:

A. A declaration that HRSA's ~~new policy on manufacturer conditions is~~(i) policy prohibiting manufacturers from requiring covered entities to provide claims data and (ii) September 18 Decision are unlawful;

B. An order vacating HRSA's ~~new~~(i) policy ~~on manufacturer conditions~~prohibiting manufacturers from requiring covered entities to provide claims data and (ii) September 18 Decision;

C. An injunction barring Defendants from taking any enforcement action based on HRSA's ~~new~~(i) policy ~~on manufacturer conditions~~prohibiting manufacturers from requiring covered entities to provide claims data and (ii) September 18 Decision;

D. Attorney's fees and costs pursuant to 28 U.S.C. § 2412; and

E. Any other just and proper relief.

~~October 6, 2021~~November 14, 2024

Respectfully Submitted,

/s/ Paul J. Zidlicky

SIDLEY AUSTIN LLP
~~William A. Sarraille (No. 431872)~~
~~wsarraille@sidley.com~~
~~(Tele.) 202-736-8195~~
Paul J. Zidlicky (No. 450196)
pzidlicky@sidley.com
(Tele.) 202-736-8013
~~Eric D. McArthur (admission application pending)~~
~~emcarthur@sidley.com~~
~~(Tele.) 202-736-8018~~
Elizabeth Hardcastle ~~(neé Kolbe)~~ (*pro hac vice* forthcoming)
ehardcastle@sidley.com
(Tele.) 202-736-8697
~~Jacquelyn E. Fradette (No. 1034328)~~
~~jfradette@sidley.com~~

~~(Tele.) 202-736-8822~~
1501 K Street, N.W.
Washington, DC 20005
(202) 736-8000
(202) 736-8711 (fax)

Trevor L. Wear (*pro hac vice* forthcoming)
twear@sidley.com
(Tele.) 312-853-7101
One South Dearborn
Chicago, IL 60603
(312) 853-7000
(312) 853-7036 (fax)

Counsel for Plaintiff Kalderos, Inc.