UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ELI LILLY AND COMPANY, *et al.*, *Plaintiffs*, v. ROBERT F. KENNEDY JR., *et al.*, *Defendants,* and 340B HEALTH, *et al.*, *Intervenor-Defendants*.	No. 24-cv-03220 (DLF)
BRISTOL MYERS SQUIBB COMPANY, *Plaintiff*, v. ROBERT F. KENNEDY JR., *et al.*, *Defendants,* and 340B HEALTH, *et al.*, *Intervenor-Defendants*.	No. 24-cv-03337 (DLF)
SANOFI-AVENTIS U.S. LLC, *Plaintiff*, v. ROBERT F. KENNEDY JR., *et al.*, *Defendants,* and 340B HEALTH, *et al.*, *Intervenor-Defendants*.	No. 24-cv-03496 (DLF)
NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff*, v. ROBERT F. KENNEDY JR., *et al.*, *Defendants*. and 340B HEALTH, *et al.*, *Intervenor-Defendants*.	No. 25-cv-00117 (DLF)

KALDEROS, INC.,
Plaintiff,
v.
UNITED STATES OF AMERICA, *et al.*,
Defendants.

No. 21-cv-02608 (DLF)

MEMORANDUM OPINION

Pharmaceutical manufacturers Eli-Lilly and Company and Lilly USA, LLC (Lilly), Bristol Myers Squibb Company (BMS), Sanofi-Aventis U.S. LLC (Sanofi), and Novartis Pharmaceutical Corporation (Novartis), and technology company Kalderos, Inc. (Kalderos), bring these actions against the U.S. Department of Health and Human Services (HHS) and the Health Resources and Services Administration (HRSA) seeking injunctive and declaratory relief. The plaintiffs allege that HRSA unlawfully rejected manufacturers' proposed rebate models for effectuating discounts provided under the 340B Drug Pricing Program, in violation of the 340B statute, *see* 42 U.S.C. § 256b, and the Administrative Procedure Act (APA). Healthcare providers 340B Health, UMass Memorial Medical Center, and Genesis Health intervened as defendants in the manufacturers' actions. Before the Court are the plaintiffs' Motions for Summary Judgment, *see* Dkt. 15,[1] No. 24-cv-3220; BMS Dkt. 17, No. 24-cv-3337; Sanofi Dkt. 27, No. 24-cv-3496; Novartis Dkt. 12, No. 25-cv-117; Kalderos Dkt. 41, No. 21-cv-2608; and the federal and intervenor-defendants' Cross Motions for Summary Judgment, *see* Dkts. 35, 36; Sanofi Dkt. 41; Kalderos Dkt. 50.

For the reasons that follow, the Court will grant the government's Cross Motions for Summary Judgment with respect to Lilly, BMS, Novartis, and Kalderos, *see* Dkt. 35; Kalderos Dkt. 50; and it will grant in part and deny in part the government's Cross Motion for Summary

[1] Unspecified docket notations throughout refer to the Lilly Docket, No. 24-cv-03320.

Judgment with respect to Sanofi, *see* Sanofi Dkt. 41. Further, it will grant in part and deny in part the intervenors' Cross Motions for Summary Judgment with respect to all the manufacturer plaintiffs, *see* Dkt. 36. Finally, the Court will deny the plaintiffs' Motions for Summary Judgment, *see* Lilly Dkt. 14; BMS Dkt. 17; Novartis Dkt. 12; Kalderos Dkt. 41, except for Sanofi's, *see* Sanofi Dkt. 27, which the Court will grant in part and deny in part.

I. BACKGROUND

A. Statutory Background

Congress enacted the 340B Drug Pricing Program to incentivize manufacturers to offer reduced drug prices to certain safety-net healthcare providers ("covered entities"), including hospitals and clinics serving low-income, uninsured, or otherwise vulnerable patient populations. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992), codified at 42 U.S.C. § 256b. A drug manufacturer opts into the 340B program by signing a Pharmaceutical Pricing Agreement (PPA) with HHS, thereby contractually agreeing to the price reductions set forth under statute. *See* 42 U.S.C. § 256b(a)(1). To incentivize participation, Congress conditions the coverage of manufacturers' products under federal Medicaid and Medicare programs on those manufacturers' participation in the 340B program. *Id*. § 1396r-8(a)(1).

Participating manufacturers must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." 42 U.S.C. § 256b(a)(1); *see Novartis Pharm. Corp. v. Johnson*, 102 F.4th 452, 464 (D.C. Cir. 2024) (manufacturers must make a "bona fide" offer of sale, which may include reasonable conditions on delivery). The 340B statute sets forth a formula for calculating the drug ceiling price—it provides that "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" may not exceed "an amount equal to the average manufacturer price [as

calculated under the Social Security Act], reduced by the rebate percentage described in [§ 256b(a)(2) of the 340B statute]." 42 U.S.C. § 256b(a)(1). That price is "strikingly generous to purchasers" and represents a substantial discount from commercial rates. *Novartis*, 102 F.4th at 456.

Congress provided guardrails in the 340B statute to "assure the integrity of the drug price limitation program." H.R. Rep. No. 102-384(II), at 16 (1992). First, the statute prohibits certain duplicate discounts—if a covered entity receives a 340B price concession, it cannot also receive a Medicaid Drug Rebate Program rebate from the manufacturer on the same drug unit. 42 U.S.C. § 256b(a)(5)(A). Second, the statute prohibits the diversion of discounts—a covered entity may not resell or transfer a unit received at the 340B price to a person who is not its patient. *Id.* § 256b(a)(5)(B). HRSA guidance provides that for an individual to qualify as a patient of a covered entity, the entity must have "established a relationship with the individual," and the entity's employee or contractor must have provided care "such that responsibility for the care provided remains with the covered entity." *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156, 55,157 (Oct. 24, 1996). If the only care rendered by the covered entity is "the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting," the drug's recipient does not qualify as a 340B patient. *Id*. at 55,158; *see also Genesis Health Care, Inc. v. Becerra*, 701 F. Supp. 3d 312, 329 (D.S.C. 2023) (noting HRSA's position that a covered entity "must have initiated the healthcare service resulting in the prescription" to a qualified 340B patient).

The 340B statute also provides procedures for manufacturers to audit or dispute discounts. *See* 42 U.S.C. § 256b(a)(5)(C), (d)(3)(A). Covered entities must allow HRSA and drug manufacturers to audit the records that "directly pertain to the entity's compliance with" the

statutory prohibitions on duplication and diversion. *Id.* § 256b(a)(5)(C). To initiate the audit process, a manufacturer submits an audit workplan to HRSA. *See* Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406, 65,410 (Dec. 12, 1996). The manufacturer is allowed to audit a covered entity only if it can demonstrate to HRSA that there is "reasonable cause," supported by "sufficient facts and evidence," to believe that a covered entity has been noncompliant. *Id.* In addition, HHS has established an Administrative Dispute Resolution mechanism to adjudicate disputes between manufacturers and covered entities. *See* 340B Drug Pricing Program, 89 Fed. Reg. 28,643 (Apr. 19, 2024); 42 C.F.R. § 10.21(a). The mechanism permits covered entities to bring complaints about overcharges, and manufacturers to bring complaints that covered entities are duplicating or diverting discounts. *See* 42 C.F.R. § 10.21(a). Before initiating an administrative dispute, however, the manufacturer must audit the covered entity. *Id.* § 10.21(a)(2); 42 U.S.C. § 256b(d)(3)(B)(iv).

In 2010, as part of the Affordable Care Act, Congress expanded the 340B program to add additional eligible covered entities, including Medicaid managed care organizations. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2501(c), 124 Stat. 119, 308 (2010). It also expanded manufacturers' bona fide offer obligations by requiring them to offer to sell all covered drugs to covered entities at 340B prices "if such drug is made available to *any* other purchaser at any price." 42 U.S.C. § 256b(a)(1) (emphasis added).

B. Administration of the 340B Program

Healthcare providers and contract pharmacies predominantly use a "product replenishment model" to track and effectuate 340B discounts. That model provides an up-front discount for drugs purchased by covered entities. *See infra.* For the three decades the 340B program has operated,

price reductions have been effectuated through an up-front discount in nearly all cases.[2] *See* Gov't Opp'n at 20, Dkt. 35; *see also* Rebate Option, 63 Fed. Reg. 35,239, 35,241–42 (June 29, 1998).

The product replenishment model works as follows: For healthcare providers dispensing prescriptions in-house, the provider initially purchases a full "package" of drug units at a commercial price; individual units are dispensed to both 340B and non-340B patients; and virtual inventory tracking software identifies how many units went to 340B patients. Testoni Decl. ¶ 3, Dkt. 36-1. After enough units are dispensed by 340B patients to fill a full package, the provider "replenishes" its inventory by purchasing another package from the manufacturer at 340B prices. Testoni Decl. ¶ 6; Administrative Record (AR) 203. Thereafter, the provider continues to track prescriptions to 340B patients and to replenish its stock at 340B prices. Testoni Decl. ¶ 6. In other words, a provider dispensing prescriptions in-house pays the commercial drug price only once—for the initial purchase—and thereafter, pays 340B prices to replenish drugs dispensed to 340B patients. *Id.* ¶ 9; AR 60–61, 203. Because providers track prescriptions virtually, most do not physically segregate their drug inventory into 340B and non-340B stock. *See* Testoni Decl. ¶ 6; Lilly MSJ at 8, Dkt. 15; Pedley Decl. ¶¶ 3–11, Dkt. 1-2. This product replenishment system reflects a change from the physical-inventory model used thirty years ago, under which providers maintained physically separate stocks of 340B and non-340B drugs. *See* Lilly MSJ at 8; BMS MSJ at 6–7, BMS Dkt. 17.

Healthcare providers also contract with third-party pharmacies to dispense drugs to 340B patients. Contract pharmacies, often themselves assisted by third-party administrators, also use a product replenishment model. The pharmacy purchases its drug inventory at commercial prices,

[2] HRSA has provided for one exception—AIDS Drug Assistance Programs receive 340B price reductions through a rebate mechanism. In 1998, the agency approved the rebates being used by those programs after notice and comment. *See* 63 Fed. Reg. 35,239 (June 29, 1998).

dispenses units to both 340B and non-340B patients, and uses software to track how many dispensed units are eligible for 340B discounts. Testoni Decl. ¶ 7; Lilly MSJ at 10–11. Once enough 340B-eligible units to fill a package are dispensed, the pharmacy notifies the covered healthcare provider. Testoni Decl. ¶ 7. The provider purchases a new drug package from a manufacturer at 340B prices, and that package is shipped to the contract pharmacy. *Id*. Notably, when dispensing through a contract pharmacy, a covered provider never pays commercial prices for 340B drugs—it only purchases replenishment packages at 340B prices. *Id.* ¶ 10.

HRSA guidance permits such contract pharmacy arrangements. Initially, in 1996, the agency allowed only providers without in-house pharmacies to contract with a single third-party pharmacy to fill 340B prescriptions. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996). In 2010, however, the agency issued expanded guidance permitting all providers to contract with an unlimited number of contract pharmacies. *See* Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,272–73 (Mar. 5, 2010). The 2010 Guidance, alongside the Affordable Care Act amendments, "prompted a significant expansion" in the 340B program and resulted in "the number of covered entities participating in the program increas[ing] from about 9,700 to 13,000 between 2010 and 2019." *Novartis*, 103 F.4th at 457.

Drug manufacturers contend that the present-day 340B program—as effectuated through the product replenishment model and facilitated by for-profit pharmacies and administrators—is rife with abuse. Between 2012 and 2019, HRSA audits found more than 1,500 instances of ineligibility, duplications, and diversions. *See* U.S. Gov't Accountability Off., GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, at 13 (Dec. 2020); *see also* H. Comm. on Energy & Com., 115th Cong., *Review of*

the 340B Drug Pricing Program 36 (Jan. 10, 2018) (describing "discount errors" as "likely" and "duplicate discounts" as "quite common"). The plaintiffs estimate that noncompliance amounts to billions of dollars of losses for drug manufacturers each year. *See* Lilly MSJ at 17; Sanofi MSJ at 27, Sanofi Dkt. 27.

The plaintiffs attribute these abuses to for-profit entities' financial incentives and to the opaqueness of inventory-tracking software. Because the 340B statute imposes no requirement that patients themselves receive discounts, covered entities, contract pharmacies, and administrators "often divvy up the spread between the discounted price and the higher insurance reimbursement rate" between themselves. *Novartis*, 103 F.4th at 457–58. Providers "use[] the 340B revenue generated by certain patients to offset losses incurred by other patients," thereby allowing those providers to offer "[healthcare] services that they might not have otherwise provided." U.S. Gov't Accountability Off., GAO-11-836*, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 17 (Sept. 2011) (2011 GAO Rep.); *see Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 730–31 (2022) (noting that "Congress . . . intended for the 340B program's drug reimbursements to subsidize other services provided by 340B hospitals"). Nonetheless, all entities involved may have "a financial incentive to catalog as many prescriptions as possible as eligible for the discount." *Novartis*, 103 F.4th at 457–58.

To identify 340B discounts, providers and contract pharmacies use proprietary software algorithms to track inventory and catalogue 340B eligibility, sometimes weeks or months after the drugs are actually dispensed. *See* Pedley Decl. ¶ 6. Those algorithms may sweep in individuals who are not patients of a covered entity or they may impose duplicate discounts for Medicaid rebates or when multiple covered entities claim the same patient. *See Novartis*, 102 F.4th at 458; 2011 GAO Rep. at 28. They also allow providers and pharmacies to influence input factors to

algorithms and select for configurations that maximize profitability. *Novartis*, 102 F.4th at 458; Lilly MSJ at 11.

Lack of HRSA oversight exacerbates noncompliance. The agency only audits about 200 covered entities per year. Pedley Decl. ¶ 6. And it does "not assess the potential for duplicate discounts in . . . Medicaid managed care,"[3] which accounts for "60 percent of Medicaid gross spending for drugs and almost 70 percent of Medicaid drug prescriptions." U.S. Gov't Accountability Off., GAO-18-480*, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 39 & n.53 (June 2018).

Manufacturers warn that unauthorized duplications may worsen under the Inflation Reduction Act of 2022, Pub. L. No. 117–169, 136 Stat. 1818. *See* Lilly MSJ at 17; BMS MSJ at 15; Novartis MSJ at 15, Novartis Dkt. 12. That Act created an inflation rebate program under Medicare Part D, administered by the Centers for Medicare & Medicaid Services (CMS), under which manufacturers must pay rebates to the Medicare program for drugs whose prices rise faster than inflation.[4] 42 U.S.C. §§ 1395w-114b(b)(1)(B), 1320f–6(c). But drugs sold at 340B prices are excluded from the inflation rebate requirement. *Id.* According to the plaintiffs, HHS lacks sufficient oversight mechanisms to identify which prescriptions will be subject to duplicate 340B and Medicare discounts, and to coordinate between HRSA and CMS, thus increasing the chances

[3] The responsibility for preventing duplications for managed care organizations falls to state Medicaid agencies. 42 U.S.C. § 1396r-8(j)(1). HHS has issued regulations outlining the steps that those state agencies must take to ensure they do not bill manufacturers for duplicate Medicaid rebates. *See* 42 C.F.R. § 438.3(s)(3).

[4] The relevant provision directs CMS to identify specific drugs to be covered under the inflation-rebate program. 42 U.S.C § 1320f-1(a)–(b); *see* Gov't Opp'n at 21. CMS will negotiate with those drugs' manufacturers to set the "maximum fair price" at which the drugs will be available to Medicare beneficiaries. *Id.* § 1320f-3. Manufacturers will be required to offer covered entities the lesser of the maximum fair price or the 340B price, *id.* § 1320f-2(d), which gives effect to the 340B statute's prohibition on duplicate discounts.

that manufacturers will be unlawfully billed for multiple rebates. Lilly's drug Jardiance, BMS's drug Eliquis, and Novartis's drug Entresto have been selected as drugs covered under the program, with inflation rebates to take effect on January 1, 2026.[5] *See* CMS, Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026 (Aug. 2024).

C. Administrative and Procedural History

Plaintiffs Lilly, BMS, Sanofi, and Novartis are drug manufacturers participating in the 340B program. Each has signed a PPA providing, in relevant part, that the "[m]anufacturer shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." AR 36. In fall 2024 and early 2025, the plaintiffs submitted proposals to HRSA to implement rebate models to effectuate their 340B obligations.[6] AR 256, 306, 348, 427. Another manufacturer, Johnson & Johnson, submitted a similar proposal around that time. AR 49. Plaintiff Kalderos has contracted with Lilly to provide a software platform to implement rebates, and Lilly's proposal to HHS expressly references the use of Kalderos's platform Truzo. AR 292.

Under Lilly, BMS, and Novartis's proposed cash rebate models, covered providers would initially purchase drugs at commercial prices. Providers would then submit claims, through a data platform operated by a third-party vendor, for cash rebates equal to the difference between the commercial price and the 340B price. AR 272 (Lilly proposing the Truzo platform owned by Kalderos); AR 330 (BMS proposing the Beacon platform owned by Berkeley Research Group);

[5] BMS and Novartis have completed maximum fair price negotiations for the inflation rebate program and are required to submit an effectuation plan to CMS by September 1, 2025. *See* BMS MSJ at 18; Novartis MSJ at 16.

[6] BMS's proposal would initially only apply to purchases of its drug Eliquis. AR 330. Sanofi's proposal would apply to purchases by disproportionate share hospitals, critical access hospitals, rural referral centers, and sole community hospitals, and consolidated health centers, AR 408, 410, and Novartis's proposal would apply to purchases by disproportionate share hospitals, AR 435.

AR 427 (Novartis proposing the Beacon platform). Rebate claims would require providers to input nonproprietary data about the quantity and dispensation of covered drugs. Manufacturers would approve or flag each claim[7] and then promptly remit rebates—Lilly represents that for all approved claims, it would make rebate payments within a week, AR 272, BMS within 10 days, AR 330, and Novartis within 7 to 10 days, AR 435.

Sanofi's proposed "credit model" differs slightly—after a covered provider purchases drugs at commercial prices, Sanofi would offer a rebate in the form of a credit that becomes effective before the provider's bill is due. AR 350. Thus, according to Sanofi, a covered provider would only ever complete payments the commercial price minus an applicable credit—that is, at the 340B price. *Id.* Sanofi's proposal also includes a patient eligibility condition, which provides that it will take responsibility for determining whether prescriptions are dispensed to a covered entity's "patient." AR 351, 360 ("Sanofi will analyze claims data . . . to determine if the individual receiving a prescription (1) is currently receiving medical care from the covered entity, and (2) receives health care services from a health care professional who is employed by or similarly affiliated with the covered entity.").

[7] The manufacturers informed HRSA that their approval processes would not result in substantial numbers of rejected claims. Lilly represents that it "[would] not 'adjudicate' any claims" or reject claims that are submitted by covered entities listed in HRSA's database that "have not already been submitted by [another] covered entity for a rebate, and that are for quantities of a medicine that could have been dispensed to a patient." AR 298. BMS represents that for Medicaid duplications, it would "deny the [Medicaid] rebate claim by the state Medicaid program, not the 340B rebate claim by the covered entity"; and for claims where the "data indicate that more than one covered entity has requested a 340B rebate on the same unit, BMS would work with the multiple claiming covered entities to determine which one should receive the 340B rebate payment." AR 330. Novartis represents that for Medicaid duplications, it would "honor the 340B rebate claim by the . . . covered entity over the [Medicaid] rebate claim by the state Medicaid program"; and "where multiple . . . covered entities submit 340B rebate claims on the same unit, Novartis would work with the covered entities to determine the appropriate recipient of the 340B rebate." AR 435.

According to the plaintiffs, the most compelling benefit of a cash (or credit) rebate model is greater transparency—manufacturers would be able to openly track which units are sold at 340B discounts and use that data to dispute unlawful duplicate rebates through HRSA. *See* Lilly MSJ at 20. Such data is currently inaccessible to manufacturers because covered entities and pharmacies do not provide access to their inventory-tracking algorithms and because HRSA purportedly imposes hurdles on audits of covered entities' records. *See*, *e.g.*, AR 431. According to the defendants, the greatest drawback for healthcare providers is the significant financial burden of providing up-front payments at commercial prices. *See* Int. Opp'n at 13; Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Rebate Option, 62 Fed. Reg. 45,823, 45,824 (Aug. 29, 1997) ("Covered entities generally preferred a discount system, because they could negotiate lower prices and needed less initial outlay of drug purchasing money."). A survey by intervenor 340B Health found that a wholesale shift to cash rebates would result in 90% of covered providers being unable to maintain their current level of services. *See* Int. Opp'n at 14; 340B Health, *Preliminary Results of 340B Health Survey: Impact of Rebates on 340B Hospitals* (Mar. 18, 2025), https://tinyurl.com/4jj3ukjf. Providers may also need to allocate substantial resources to submitting and administrating rebate claims. *See* Int. Opp'n at 13.

After the manufacturer plaintiffs submitted their proposals to HRSA, the parties engaged in multiple discussions about the proposals. The agency requested, and the manufacturers provided, details about the implementation of the rebate models, the criteria for claims approval, timelines for adjudication, and the reconsideration mechanisms available to covered entities. *E.g.*, AR 292, 295, 342, 380, 383. HRSA raised concerns that a "shift" to the cash rebate model "would disrupt how the 340B Program has operated for over thirty years," and that as "a result of this shift,

covered entities, including those which primarily serve rural and underserved populations, would need to pay significantly higher prices on prescription drugs at the time of purchase." AR 66.

To date, HRSA has not approved the plaintiffs' rebate proposals. But the agency has informed drug manufacturers that implementing a rebate model requires agency approval. AR 292, 342, 380, 439. In letters to Lilly, BMS, and Novartis, the agency asserted that "[t]o date, the Secretary has not provided for such rebate as proposed by [the manufacturer]. 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 [the manufacturer] has proposed." *Id*. HRSA also issued follow-on letters to Johnson & Johnson and Sanofi, warning that implementing rebates without agency approval could result in the termination of their PPAs. AR 203, 425. In a December 13, 2024 violation letter to Sanofi, the agency also found that its credit rebate and patient eligibility condition violated the 340B statute. AR 424. HRSA published the letters to Johnson & Johnson and Sanofi on its website, and it also posted a blanket warning that "implementing a rebate proposal without Secretarial approval would violate Section 340B(a)(1) of the Public Health Service Act." Health Res. & Servs. Admin., *340B Drug Pricing Program*, https://www.hrsa.gov/opa (last updated Apr. 2025).

The four manufacturer plaintiffs filed separate actions, asserting claims under the APA and the Due Process Clause of the Fifth Amendment. *See* Dkt. 1; BMS Dkt. 1; Sanofi Dkt. 1; Novartis Dkt. 1. The Court granted leave for 340B Health, UMass Memorial Medical Center, and Genesis Health to intervene as defendants in each manufacturers' action. *See* Minute Order of Feb. 6, 2025. The manufacturer plaintiffs moved for summary judgment. *See* Dkt. 15; BMS Dkt. 17;

Sanofi Dkt. 27; Novartis Dkt. 12. Kalderos also moved for summary judgment.[8] *See* Kalderos Dkt. 51. The Court declined to consolidate the actions, but it accepted the parties' proposal for a joint briefing and hearing schedule. *See* Minute Order of Feb. 24, 2025. The federal defendants filed a combined cross motion for summary judgment against Lilly, BMS, and Novartis, *see* Dkt. 35, and separate cross motions for summary judgment against Sanofi and against Kalderos, *see* Sanofi Dkt. 41; Kalderos Dkt. 50. The intervenor-defendants filed a combined cross motion for summary judgment against the four manufacturer plaintiffs. *See* Dkt. 36. On April 29, 2025, the Court held a joint hearing on the summary judgment motions. Following that hearing, on May 2, 2025, the agency filed a notice informing the Court that it "continues to carefully evaluate its options" and "expects to be in a position to provide guidance for stakeholders in thirty days." May 2 Notice at 2, Dkt. 48.

II. LEGAL STANDARDS

Under Rule 12(b)(1) of the Federal Rules of Civil Procedure, a defendant may move to dismiss an action for lack of subject-matter jurisdiction. Fed. R. Civ. P. 12(b)(1). Federal law empowers federal district courts to hear only certain kinds of cases, and it is "presumed that a cause lies outside this limited jurisdiction." *Kokkonen v. Guardian Life Ins.*, 511 U.S. 375, 377 (1994). When deciding a Rule 12(b)(1) motion, the court must "assume the truth of all material factual allegations in the complaint and construe the complaint liberally, granting plaintiff the

[8] Kalderos initially filed its action in October 2021, challenging HRSA's policy of prohibiting manufacturers from imposing certain conditions on the distribution of 340B covered drugs. Kalderos Dkt. 1. Following the D.C. Circuit's decision in *Novartis*, 102 F.4th at 462, which affirmed this Court and permitted reasonable conditions on distribution, the Court granted Kalderos leave to file an amended complaint. *See* Kalderos Am. Compl., Kalderos Dkt. 34. The amended complaint now brings similar APA claims as the manufacturer plaintiffs, challenging HRSA's imposition of a preapproval requirement on Lilly's proposed rebate model, as effectuated through Kalderos's data platform. *Id.* ¶¶ 111–43.

benefit of all inferences that can be derived from the facts alleged, and upon such facts determine [the] jurisdictional questions." *Am. Nat. Ins. v. FDIC*, 642 F.3d 1137, 1139 (D.C. Cir. 2011) (citations and quotation marks omitted). A court that lacks jurisdiction must dismiss the action. Fed. R. Civ. P. 12(b)(1), 12(h)(3).

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment is appropriate if the moving party "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 247–48 (1986). A "material" fact is one that could affect the outcome of the lawsuit. *See Liberty Lobby*, 477 U.S. at 248; *Holcomb v. Powell*, 433 F.3d 889, 895 (D.C. Cir. 2006). A dispute is "genuine" if a reasonable jury could determine that the evidence warrants a verdict for the nonmoving party. *See Liberty Lobby*, 477 U.S. at 248; *Holcomb*, 433 F.3d at 895.

In an APA case, summary judgment "serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006). The Court will "hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id.* § 706(2)(C), or "unsupported by substantial evidence," *id.* § 706(2)(E). In evaluating an agency's interpretation of a statute, "courts need not and under the APA may not defer to an agency interpretation of the law simply because a statute is ambiguous." *Loper Bright Enters. v. Raimondo,* 603 U.S. 369, 413 (2024). Rather, the Court must "exercise independent judgment" in construing the statute. *Lake Region Healthcare Corp. v. Becerra*, 113 F.4th 1002, 1007 (D.C. Cir. 2024) (citation omitted).

In an arbitrary and capricious challenge under § 706(2)(A), the core question is whether the agency's decision was "the product of reasoned decisionmaking." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 52 (1983); *see also Nat'l Telephone Coop. Ass'n v. FCC*, 563 F.3d 536, 540 (D.C. Cir. 2009) ("The APA's arbitrary-and-capricious standard requires that agency rules be reasonable and reasonably explained."). The court's review is "fundamentally deferential—especially with respect to matters relating to an agency's areas of technical expertise." *Fox v. Clinton*, 684 F.3d 67, 75 (D.C. Cir. 2012) (quotation marks and alteration omitted). A court "is not to substitute its judgment for that of the agency." *State Farm*, 463 U.S. at 43. "Nevertheless, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Id.* (internal quotation marks omitted). When reviewing that explanation, a court "must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Id.* (internal quotation marks omitted). The party challenging an agency's action as arbitrary and capricious bears the burden of proof. *Pierce v. SEC*, 786 F.3d 1027, 1035 (D.C. Cir. 2015).

III. ANALYSIS

These actions challenge HRSA's failure to approve the plaintiffs' proposed rebate models. To date, HRSA has not finally rejected Lilly, BMS, or Novartis's proposals—rather, it has informed those manufacturers that it cannot "approve or disapprove" their rebate models "to date." AR 292, 347, 439. With respect to the agency's proffered approval timeline, the parties face countervailing pressures. The agency asserts that it needs longer to complete its review of the

varied proposals manufacturers began submitting in July of 2024,[9] which represent a large-scale shift in the way the 340B program has operated for three decades. *See* Gov't Reply at 4, Dkt. 47. Drug manufacturers, on other the hand, continue to accumulate losses from unlawful duplications and diversions; and Lilly, BMS, and Novartis face the prospect that those losses will increase when the Medicaid inflation program takes effect on January 1, 2026. *See* Apr. 29 Hr'g Rough Tr. at 41. With these considerations in mind, the Court turns to the plaintiffs' challenges.

The plaintiffs contend, first, that HRSA acted in excess of its authority under the 340B statute by requiring manufacturers to obtain preapproval for their rebate models. *See* 5 U.S.C. § 706(2). Second, the plaintiffs contend that the agency acted arbitrarily and capriciously in imposing a preapproval requirement and in failing to approve their proposals. *See id.* § 706(2)(A). Sanofi also argues that the agency's rejection of its credit rebate and patient eligibility condition was arbitrary and capricious. Third, BMS and Novartis contend that the agency's failure to prevent unlawful discounts deprives them of property interests in violation of the Fifth Amendment's Due Process Clause. The Court will address the merits of each contention in turn, but first, it will evaluate whether Kalderos has standing to bring suit.

A. Standing as to Kalderos

The federal defendants seek to dismiss Kalderos's action on standing grounds. *See* Gov't Opp'n to Kalderos at 6–10, Kalderos Dkt. 50. To establish standing, a plaintiff must show: (1) an "injury in fact"; (2) a "causal connection between the injury" and the challenged action; and (3) a likelihood that the "injury will be redressed by a favorable decision." *Lujan v. Defs. of Wildlife*,

[9] The Court recognizes that data platforms such as Kalderos began discussions with the agency as early as February 2019. *See* AR 465. Nonetheless, the agency could not have been positioned to evaluate the details of any rebate proposal—for example, the claims processing timeline, the adjudication process, and or the details of implementation with respect specific covered entities—before the manufacturers' involvement in July 2024.

504 U.S. 555, 560–61 (1992) (internal quotation marks omitted). The burden lies with the plaintiff to present "substantial evidence of a causal relationship between the government policy and the third-party conduct, leaving little doubt as to causation and the likelihood of redress." *Arpaio v. Obama*, 797 F.3d 11, 20 (D.C. Cir. 2015) (cleaned up). A plaintiff who is not the direct subject of a government regulation will generally find it "'substantially more difficult' to establish" standing. *Lujan*, 504 U.S. at 562 (*quoting Allen v. Wright*, 468 U.S. 737, 758 (1984)).

Here, Kalderos has alleged a cognizable injury in the form of future economic losses arising from the regulatory impediments to the use of its data platform Truzo. "That qualifies as an injury in fact." *Energy Future Coal. v. EPA*, 793 F.3d 141, 144 (D.C. Cir. 2015). Although HRSA's regulatory actions are directed toward drug manufacturers and not data platforms, the agency's actions nonetheless impede Kalderos from selling its software services. Thus, both the manufacturers and Kalderos "are 'an object of the action (or forgone action) at issue.'" *Id.* (quoting *Lujan*, 504 U.S. at 561–62) ("If the Government prohibits or impedes Company A from using Company B's product," ordinarily, "Company B [will] have standing to sue."). And the administrative record here clearly demonstrates causation and redressability. Lilly has contractually committed to using Kalderos's data platform, and Lilly's proposal to HRSA expressly highlights the use of Truzo to effectuate its cash rebate model. AR 272. There is little question that the impediments to Lilly's proposal also hinder Kalderos from generating revenue, and that Kalderos's requested injunctive relief would redress its alleged injury. *Energy Future*, 793 F.3d at 144–45. Accordingly, the Court finds that Kalderos has standing to challenge the HRSA actions at issue.

B. Preapproval Requirement

Turning to the merits of the plaintiffs' claims, the Court first considers whether the preapproval requirement exceeded the agency's statutory authority. To evaluate the scope of

HRSA's authority, the Court begins with the text of the 340B statute. *Oklahoma v. Castro-Huerta*, 597 U.S. 629, 642–43 (2022). The statute provides that covered entities are entitled to purchase drugs at or below the statutory price cap. The first provision of the relevant text, known as the "purchased by" provision, *Sanofi Aventis v. HHS*, 58 F.4th 696, 700 (3d Cir. 2023), states:

> The 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 . . . reduced by the rebate percentage described in paragraph (2).

42 U.S.C. § 256b(a)(1). That provision sets forth a formula for calculating the maximum price[10]—the "amount to be paid"—to which manufacturers are agreeing when they sign a PPA. The second provision of the text, known as the "shall offer" provision, *Sanofi*, 58 F.4th at 703, mandates that manufacturers must make bona fide offers of sale:

> Each such agreement shall 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.

42 U.S.C. § 256b(a)(1); *see Novartis*, 102 F.4th at 464. Taken together, the "purchased by" provision binds manufacturers to a reduced price, and the "shall offer" provision requires manufacturers to actually make offers to sell their drugs at that price.[11] The statute does not grant

[10] That price is calculated by taking the "average manufacturer price" and subtracting a percentage reflective of the rebates paid by manufacturers to state Medicaid agencies over the last quarter. *See id.* § 256b(a)(2)(A)(i) (defining rebate percentage as the average total rebate required under the Medicaid Statute, 42 U.S.C. § 1396r–8(c), over the previous calendar quarter).

[11] The intervenors argue that the "shall offer" provision categorically prohibits rebate models because the statutory language requires an up-front discount. *See* Int. Opp'n at 21. The Court disagrees. Although the statute provides that manufacturers must make offers "at or below the applicable ceiling price," that same paragraph also contemplates that the "amount to be paid" by a covered entity must "tak[e] into account any rebate or discount." 42 U.S.C. § 256b(a)(1). The statute thus explicitly contemplates a rebate mechanism.

HHS general rulemaking authority, but the agency has issued guidance "interpreting and implementing the scheme." *Novartis*, 102 F.4th at 456.

Crucially, the statute states that in implementing price reductions, "any rebate or discount" taken into account shall be "as provided by the Secretary." 42 U.S.C. § 256b(a)(1). The term "provide" means "to have as a condition" or to "stipulate." *Provide*, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/provide. Put another way, the statute contemplates that the Secretary may "have as a condition" or "stipulate" how any rebate or discount is accounted for in the price ultimately paid by covered entities. That plain text provides authorization for the agency to regulate the implementation of price reductions. And "[w]hat legislative history there is reinforces the text[ual]" authorization to the agency. *See Fed. Educ. Ass'n Stateside Region v. FLRA*, 104 F.4th 275, 284 (D.C. Cir. 2024). The House Committee on Energy and Commerce report accompanying the 1992 legislation noted that 340B price reductions "would be implemented, *at the discretion of the Secretary*, either by a point-of-purchase discount, a rebate, or other mechanism." H.R. Rep. No. 102-384(II), at 8, 12, 16 (emphasis added).

HRSA has previously exercised that authority to adjust manufacturers' price reduction obligations in the face of operational challenges. For example, drugs newly introduced to market have no calculable Medicaid rebate percentage over the last calendar quarter, as necessary to input into the 340B statutory formula. Thus, agency regulations permit manufacturers to estimate the appropriate discount until sufficient market data has been generated. *See* 42 C.F.R. § 10.10(c). Likewise, when the Medicaid rebate percentage exceeds the up-front price of the drug, manufacturers would face negative prices and be obligated to pay the purchasers of their drugs under the 340B formula. In that scenario, agency regulations adjust the 340B price to $0.01. *Id.*

§ 10.10(b); *see* 82 Fed. Reg. 1210, 1214–17 (Jan. 5, 2017). Such regulations are further evidence that the agency has the authority to condition how 340B price reductions are implemented.

Nor has the agency disclaimed that authority by not preapproving other 340B price reduction models. The plaintiffs highlight that HRSA did not *ex ante* approve the rebates currently used by AIDS Drug Assistance Programs. Lilly MSJ at 20–22. Those programs' unique "purchasing systems" initially "prevented their participation in the section 340B discount program," so they began using a rebate mechanism to access price reductions. *See* 62 Fed. Reg. at 45,824. In 1998, HRSA subjected that mechanism to notice and comment after the rebate program began. *Id.* But nothing in the guidance HRSA issued during that process suggests that the agency lacked the authority to block those rebates at any time. *See id.*; 63 Fed. Reg. at 35,239. Nor does the statutory text restrict HRSA to "provid[ing]," 42 U.S.C. § 256b(a)(1), for the manner of a rebate or discount only after manufacturers put a payment system in place. Thus, that HRSA approved the AIDS Drug Assistance Program rebates after their implementation does not suggest that it lacked the authority to preapprove them. Likewise, that the agency has not exercised its approval authority with respect to the product replenishment model does not suggest that it could not do so. *Cf. Nat'l Petroleum Refiners Ass'n v. FTC*, 482 F.2d 672, 693–95 (D.C. Cir. 1973) (finding that FTC has rule-making authority despite the agency's lack of historical exercise of that authority).

The plaintiffs further contend that any conditions the agency seeks to impose on rebates must be explicitly set forth in manufacturers' PPAs. But PPAs are "form contract[s] implementing the statute," which "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 114, 117–18 (2011) ("The statutory and contractual obligations, in short, are one and the same."). The 340B

statute plainly authorizes HRSA to "provide[]" for the implementation of any rebate or discount, *see* 42 U.S.C. § 256b(a)(1), and that authority is incorporated into the plaintiffs' PPAs, *see Astra*, 563 U.S. at 118. Thus, the plaintiffs cannot claim that they are immune from the agency's statutory approval authority simply because their PPAs do not specifically address the approval of their present proposals.

Finally, Kalderos attempts to reframe the preapproval requirement as an impermissible prohibition on manufacturers' requiring covered entities to provide claims data. Kalderos MSJ at 22; *see Novartis*, 102 F.4th at 469 (authorizing manufacturers to condition drug delivery on the provision of certain claims data). But that characterization is too narrow. The preapproval requirement is not specifically targeted toward covered entities' submission of claims data; rather, it regulates the manufacturers' proposed rebate mechanisms as a whole. Indeed, HRSA's letters to manufacturers emphasize that the agency's primary concern is the "shift" from up-front discounts to rebates, which would "disrupt how the 340B Program has operated for over thirty years." *E.g.*, AR 292. Nothing in those letters suggest the agency purported to be imposing a standalone prohibition on the provision of claims data, outside the context of a broader shift to rebates. Accordingly, the Court finds the agency's actions do not contravene the D.C. Circuit's decision in *Novartis*.

In sum, the Court finds that HRSA did not act contrary to law by requiring the plaintiffs to obtain approval before implementing their proposed rebate models. Therefore, it will deny the plaintiffs' motions for summary judgment and grant the defendants' cross motions for summary judgement upholding the preapproval requirement. To the extent that the intervenors-defendants seek a declaration that rebates are categorically prohibited under the 340B statute, however, that portion of their cross motion will be denied.

C. Arbitrary and Capriciousness

Next, the plaintiffs argue that HRSA's disapprovals of their rebate models were arbitrary and capricious. First, they argue that the agency had no basis for treating their proposals differently from the AIDS Drug Assistance Program rebate model or the product replenishment model, which were not subject to agency preapproval. And second, they argue that the agency failed to consider the effects of unlawful duplications and diversions and of manufacturers' lack of access to claims data. The Court disagrees in large part. The agency adequately distinguished the plaintiffs' proposed rebate models from previously approved models, and it has not yet made a final decision on whether to accept the Lilly, BMS, and Novartis rebate proposals. With respect to Sanofi's credit rebate proposal, however, the agency has made a final decision, and it has done so without providing adequate justification for its decision. Accordingly, the Court will remand that decision to the agency for further consideration of Sanofi's proposal.

1. Differential Treatment

The "great principle that like cases must receive like treatment" is "black letter administrative law." *Baltimore Gas and Electric Co. v. FERC*, 954 F.3d 279, 286 (D.C. Cir. 2020) (citation and quotation marks omitted). If an agency reaches different results in two apparently similar cases, it must "point to a relevant distinction between the two cases." *Westar Energy, Inc. v. FERC*, 473 F.3d 1239, 1241 (D.C. Cir. 2007). That is, it must "offer a rational explanation," *Colorado Interstate Gas Co. v. FERC*, 850 F.2d 769, 774 (D.C. Cir. 1988), for why those cases "are not similarly situated," *BP Energy Co. v. FERC*, 828 F.3d 959, 968 (D.C. Cir. 2016). And the distinctions drawn must be rooted in "relevant regulatory factors." *Grayscale Invs., LLC v. SEC*, 82 F.4th 1239, 1245 (D.C. Cir. 2023).

The plaintiffs contend that HRSA violated this tenet by permitting rebates for AIDS Drug Assistance Programs without preapproval, while insisting that drug manufacturers' present proposals must be preapproved. Lilly MSJ at 30–36. But the agency has provided a rational explanation for that difference: AIDS Drug Assistance Programs' purchasing systems differ from other covered entities, so they have trouble accessing statutorily mandated price reductions through up-front discounts. 62 Fed. Reg. at 45,824. As the agency explained in its 1998 guidance:

> Although the [up-front] discount system is functioning successfully for most covered entities, most [AIDS Drug Assistance Programs] have drug purchasing systems that have prevented their participation in the section 340B discount program. The use of a rebate option . . . should allow these groups to access section 340B pricing.

62 Fed. Reg. at 45,824. For this reason, HRSA approved rebates to allow those programs to access 340B price reductions.

The plaintiffs have not suggested that other covered entities face similar challenges in accessing 340B prices. Moreover, unlike the plaintiffs' proposals, the AIDS Drug Assistance Program rebates were approved after notice and comment—with the consent of covered entities—and offered as an *optional* mechanism for covered programs. *See id*. Commenters highlighted the "unique needs of the [AIDS Drug Assistance Programs]," 63 Fed. Reg. at 35,242, and asserted that their "(favorable) response to the recognition of a rebate program for the [AIDS Drug Assistance Programs] would be different if [HRSA] proposed a rebate program for all covered entities," *id.* at 35,241–42. The agency recognized those concerns, *see id.*, and has not approved a rebate model for any other type of covered entity since. Given those "relevant distinction[s]" between AIDS Drug Assistance Programs and other covered entities, *see Westar Energy*, 473 F.3d at 124, the Court cannot say that the agency's disproval of a broader rebate model was arbitrary and capricious.

Nor are the plaintiffs' proposed rebate models sufficiently similar to the product replenishment model. *Contra* Lilly MSJ at 31–34. Most critically, a cash rebate model shifts the initial outlay for drug costs from manufacturers to covered entities. AR 203 (setting forth HRSA's determination that "under [manufacturers' rebate proposals], covered entities would be forced to pay a higher price point up front for *every* purchase"). Cash rebates would require providers to spend significantly more up front on each transaction, in contrast to the replenishment model, under which covered providers typically pay commercial prices only once. AR 203; *see* Testoni Decl. ¶ 9. Before a rebate is received, covered providers would effectively float manufacturers the 340B discount value. AR 568; *see* Int. Opp'n at 2. That financial burden on providers has factored into HRSA's preference for up-front discounts since the 340B program's inception. *See* 62 Fed. Reg. at 45,824 ("Covered entities generally preferred [an up-front] discount system, because they . . . needed less initial outlay of drug purchasing money."). Providers have informed HRSA that under the plaintiffs' proposals, "340B hospitals will be forced to incur higher carrying costs," those carrying costs would "reduce[] the hospitals' resources available for other patient care," and "smaller covered entities that already are operating on razor thin margins would be unable to handle these upfront costs." AR 568; *see* H.R. Rep. No. 102-384(II) at 12 (explaining the program's purpose of enabling covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services"). And as the D.C. Circuit has noted, where conditions such as carrying costs are "onerous enough to effectively increase the contract 'price,'" those conditions may violate the 340B ceiling price. *Novartis*, 102 F.4th at 456. Thus, the impact of a rebate float was a relevant factor the agency was entitled to take into consideration.

Moreover, the agency has explained that while covered entities "voluntarily choose to use replenishment processes," they have voiced strong opposition to the proposed cash rebate models. AR 203; *see* AR 568; AR 570 (raising "serious concerns about [manufacturers'] proposed use of rebates to avoid compliance with 340B program requirements"); AR 610 (suggesting rebates may "put roadblocks between hospitals and the statutorily required 340B discounts"); AR 585 (same). In its publicly-posted letter to Johnson & Johnson, HRSA highlighted those "fundamental differences" as relevant to its decision to subject rebate models to agency approval. AR 202–03. Covered entities are among the intended beneficiaries of the 340B statute, and the agency was entitled to consider their preferences as a relevant factor. Given those differences, the Court finds that HRSA has rationally explained the "relevant distinction[s]" between the plaintiffs' rebate proposals and the product replenishment model. *Westar Energy*, 473 F.3d at 1241.

Accordingly, the Court will deny the plaintiffs' motions and grant the defendants' cross motions with respect to the claims that HRSA's differential application of a preapproval requirement was arbitrary and capricious.

2. Failure to Consider the Benefits of a Rebate Model

The plaintiffs further argue that HRSA arbitrarily and capriciously rejected their proposals without adequately considering important benefits—that a rebate model would help prevent currently rampant unlawful discounts and provide manufacturers with the claims data necessary to meaningfully engage in dispute resolution. *See* Lilly MSJ at 39; Novartis MSJ at 33. An agency action is arbitrary and capricious if the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before [it], or [the explanation] is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43. An aspect of the problem is "by

definition" important if it is "statutorily mandated." *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1216 (D.C. Cir. 2004).

a. Lilly, BMS, Novartis, and Kalderos[12]

Lilly, BMS, and Novartis take issue with the agency's failure to consider the anti-diversion and anti-duplication benefits of their proposals. The "potential abuses" of "unlawful diversion and duplicate discounts" have been widely documented, *Novartis*, 102 F.4th at 456, and the Court will not repeat them here.

Given the intersection between the 340B program and the forthcoming Medicaid inflation rebate program, it is likely that these risks will be exacerbated in January 2026 when the program is scheduled to take effect, *see* 42 U.S.C. § 1320f-2(d). Novartis and BMS, in particular, face pressing deadlines because they must submit a Medicaid inflation rebate implementation plan to CMS by September 1, 2025. *Id.* at 286. To date, CMS has informed manufacturers that it "will not . . . assume responsibility for nonduplication of discounts between the 340B ceiling price and [Medicaid inflation rebates]." *See* CMS, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Section 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027, at 231 (Oct. 2, 2024) (2024 Negotiation Program Guidance). Although HRSA represents that it plans to "coordinate . . . [with CMS] to provide and share information to support compliance with each agency's respective program requirements," *id.* at 232, the absence of a definitive oversight plan to date is concerning.

[12] The Court notes that any analysis applicable to Lilly should be construed as also applying to Kalderos because any decision regarding Kalderos's data platform is inherently tied to the agency's decision about Lilly's cash rebate proposal.

Lilly, BMS, and Novartis also take issue with the agency's failure to consider that their cash rebate proposals would generate the claims data necessary to give teeth to statutory audit and Alternative Dispute Resolution procedures. To initiate an audit of a 340B covered entity, manufacturers must provide evidence of a suspected violation. 61 Fed. Reg. at 65,410. And to bring any dispute resolution claim with HRSA, manufacturers must first audit the counterparty covered entity. 42 U.S.C. § 256b(d)(3)(A). Likewise, to dispute any duplicate inflation rebate with CMS, manufacturers must "provide documentation [to CMS] demonstrating the claim was 340B-eligible." 2024 Negotiation Program Guidance at 230. But such documentation is inaccessible, according to the plaintiffs, because the product replenishment model does not make transaction data reasonably available. *E.g.*, BMS MSJ at 16. Although the agency does not disclaim manufacturers' right to "impose data-reporting conditions on covered entities," and proposes that other data collection mechanisms may effectuate the same ends, *see* Gov't Reply at 10, the administrative record contains little evidence one way or another as to the efficacy of alternative data collection mechanisms.

Without question, unlawful duplications and diversions, and manufacturers' *de facto* access to audit procedures, are important and relevant factors for HRSA to consider in assessing the plaintiffs' cash rebate proposals. Nonetheless, the Court recognizes that the agency has not made any final decision on Lilly, BMS, or Novartis's proposals. *See id.* at 11 ("[T]he Agency has not ruled out providing for rebate models if given sufficient time to assess the rebate models."). To the contrary, HRSA's letters to those plaintiffs merely assert the agency's preapproval authority and do not make any findings on whether the substance of those proposals violate 340B statutory

requirements.[13] Thus, the administrative record supports the agency's present position that it has not rendered any substantive final rejection of those plaintiffs' proposals. The agency reiterated before this Court, in the motions hearing and in its May 2 filing, that it is "continu[ing] to carefully evaluate its options" and expects to provide further guidance within thirty days. May 2 Notice at 2; *see* April 29 Hr'g Rough Tr. at 61 ("[I]t's important for me to reiterate that we didn't say no, never, you can never implement these rebates. We said not now.").

In light of the agency's ongoing review, it would be premature for the Court to decide at this juncture whether HRSA has considered all relevant factors with respect to the proposals presented by Lilly, Novartis, BMS, and Kalderos. *See Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs*, 417 F.3d 1272, 1281 (D.C. Cir. 2005) ("The fitness of an issue for judicial decision depends on whether it is purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final." (cleaned up)). Accordingly, at this time, the Court will deny those plaintiffs' motions for summary judgment and grant the defendants' cross motions.

b. Sanofi

Sanofi, however, is differently situated from the other plaintiffs: HRSA's December 13, 2024 violation letter determined that Sanofi's "credit proposal would require certain covered entity types to purchase certain Sanofi product at prices that exceed [the 340B ceiling price]. This . . . *violates* Section 340B(a)(1)." AR 425 (emphasis added). That language is fairly read as a determinative legal finding and final rejection. Accordingly, the Court will evaluate whether the

[13] *See* AR 292 ("To date, the Secretary has not provided for such rebate as proposed by Lilly."); AR 347 ("[T]o date, the Secretary has neither approved or disapproved BMS's rebate model."); AR 439 ("To date, the Secretary has not provided for such a rebate model . . . [and] has neither approved or disapproved Novartis' rebate model.").

agency's rejection of Sanofi's credit model and patient eligibility condition was arbitrary and capricious.

Like the other plaintiffs, Sanofi challenges the agency's failure to consider the prevalence of unlawful duplications and diversions under the product replenishment model, as well as drug manufacturers' lack of access to claims data. Sanofi MSJ at 7, 28–30, 33. According to Sanofi, its proposed credit rebate model and patient eligibility condition would substantially curb statutory violations and generate the data necessary to give teeth to the Alternative Dispute Resolution process. *Id.* at 29, 33. And Sanofi has repeatedly and specifically raised those concerns to HRSA. AR 357–62, 387–89; 408–09.

But as the agency conceded in the April 29 hearing, the administrative record does not address concerns that Sanofi and the other plaintiffs raised about unlawful duplications and diversions. April 29 Hr'g Rough Tr. at 56 ("[F]rom the agency, there isn't a specific spot [in the administrative record] where we talk about that."). And the agency provided no explanation for its failure to address these valid concerns. *Id*. Nor does the administrative record address manufacturers' concerns about lack of access to claims data. That lack of consideration is dispositive. *Pub. Citizen*, 374 F.3d at 1216.

Given the agency's admission and the dearth of record evidence, the Court will grant Sanofi's motion for summary judgment on the grounds that HRSA failed to provide a reasoned explanation for disregarding concerns about duplications and diversions and data access. *See State Farm*, 463 U.S. at 43. It will vacate the portions of the December 13 violation letter rejecting Sanofi's credit rebate and patient eligibility condition, and it will remand to the agency for further consideration.

To be clear, this decision does not vacate the agency's preapproval requirement, and therefore Sanofi may not unilaterally implement its rebate proposal at this juncture. Nor is the Court placing a thumb on the scale in terms of balancing the need to curb duplications and diversions and other statutory objectives. Finally, because the Court will vacate the agency's rejection of Sanofi's entire proposal, it will not reach Sanofi's alternative arguments that the agency erred in finding the credit rebate violative of the statutory ceiling price, *see* Sanofi MSJ at 17–26, or in prohibiting the patient eligibility condition, *id.* at 29–33. The agency shall reconsider and explain whether and why the specific conditions in Sanofi's proposal—for example, those that permit manufacturers to adjudicate claims or impose a 30-day deadline for claims submission, *see* AR 410–12—improperly usurp the agency's authority over the dispute resolution process or otherwise violate the 340B statute.

D. Due Process Violations

Finally, the Court turns to Novartis and BMS's claims that the failure to approve their cash rebate models procedurally and substantively deprives them of property interests, in violation of the Fifth Amendment. Property interests cognizable under the Fifth Amendment must be "created and their dimensions . . . defined by existing rules or understandings that stem from an independent source such as state law." *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 577 (1972). To assert a procedural due process claim, a plaintiff must show that the deprivation of its property interest occurred without "the opportunity to be heard 'at a meaningful time and in a meaningful manner.'" *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976) (quoting *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965)). The process due is "flexible and calls for such procedural protections as the particular situation demands." *Morrissey v. Brewer*, 408 U.S. 471, 481 (1972). To assert a substantive due process claim, a plaintiff must show that the property deprivation, regardless of

the process used, rises to an "abuse of power" that "shocks the conscience" or "interferes with rights implicit in the concept of ordered liberty." *County of Sacramento v. Lewis*, 523 U.S. 833, 846–47 (1998) (citation and quotation marks omitted); *see Tri Cnty. Indus., Inc. v. District of Columbia*, 104 F.3d 455, 459 (D.C. Cir. 1997).

To begin, the plaintiff manufacturers voluntarily choose to participate in and offer discounts under the 340B and Medicaid and Medicare programs. *See e.g.*, *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442 (8th Cir. 1984) ("Despite the financial inducement to participate in Medicaid, a nursing home's decision to do so is nonetheless voluntary."). The voluntariness of these programs weakens any claim that monetary losses incurred due to programmatic inefficiencies amount to protected property under the Fifth Amendment. *See Se. Arkansas Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016); *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 23-cv-1103 (MPS), 2024 U.S. Dist. LEXIS 117413, *21 (D. Conn. Jul. 3, 2024). But even assuming that those losses are protected property, the statutory audit and Alternative Dispute Mechanism procedures in the 340B statute provide adequate process. *See Lujan v. G & G Fire Sprinklers*, 532 U.S. 189, 197 (2001) (providing that post-deprivation adjudication was sufficient process for a state contractor allegedly deprived of payments). The agency points to at least 37 instances before 2024 where HRSA received an audit workplan and determined that the manufacturer could proceed with the audit. *See* Britton Decl. ¶ 15; *Univ. of Wash. Med. Ctr. v. Becerra*, No. 24-cv-2998 (RC) (D.D.C. Dec. 20, 2024), Dkt. 22-1. Accordingly, the Court cannot say that those statutory adjudication procedures are so inadequate as to amount to a procedural due process violation.

Nor does the Court find—even crediting the plaintiffs' high-end estimate that up to five percent of 340B transactions are duplications and diversion—that this error rate is so high as to

shock the conscience or amount to a substantive due process violation. *Tri Cnty. Indus.*, 104 F.3d at 459 (noting that "unlike procedural due process, under which there may be recovery even for nominal damages," a substantive due process claim has "a substantiality requirement built in" and is limited to "actions that in their totality are genuinely drastic").

Accordingly, the Court will deny BMS and Novartis's motions for summary judgment and grant the defendants' cross motions on the plaintiffs' constitutional claims.

CONCLUSION

For these reasons, the Motions for Summary Judgment filed by Lilly, BMS, Novartis, and Kalderos are denied, and Sanofi's Motion for Summary Judgment is granted in part and denied in part. The government's Cross Motions for Summary Judgment are granted with respect to Lilly, BMS, Novartis, and Kalderos; and granted in part and denied in part with respect to Sanofi. The intervenors' Cross Motions for Summary Judgment are granted in part and denied in part. A separate order consistent with this decision accompanies this memorandum opinion.

DABNEY L. FRIEDRICH
United States District Judge

May 15, 2025