UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRISTOL MYERS SQUIBB COMPANY,

Plaintiff,

v.

DOROTHY FINK, in her official capacity as ACTING SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

Case No. 1:24-cv-03337 (DLF)

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF BRISTOL MYERS SQUIBB COMPANY'S MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF CONTENTS-Continued

Page

TABLE OF AUTHORITIES

Page(s)

CASES:

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

CONSTITUTIONAL PROVISIONS:

STATUTES AND REGULATIONS:

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

OTHER AUTHORITIES:

TABLE OF AUTHORITIES—Continued

Page(s)

INTRODUCTION

A drug manufacturer participating in the 340B Drug Pricing Program must offer reduced prices on its drugs. Congress set out the formula for calculating that 340B "ceiling price" in the 340B statute. That much is undisputed. Federal law leaves open how the 340B ceiling price may be given, however. The statute supplies two options: Through a rebate paid after an initial purchase at market prices or through a discount at the time of purchase. The two stand on equal footing under the statute, which subjects neither to administrative preapproval.

The 340B Program confers a significant benefit on "covered entities"—certain hospitals and clinics that meet defined statutory criteria—because it makes drug manufacturers' products available at the statute's special below-market rates. But that benefit, because it is so substantial, is subject to checks that Congress wrote into the 340B statute. One important safeguard is that the manufacturer does not have to give both a 340B price concession and a Medicaid Drug Rebate Program (MDRP) rebate on the same prescription.

Although covered entities purchase medicines at significantly reduced prices, there is no requirement to pass through to patients any savings or amounts otherwise reaped above the drug's acquisition cost. The statute does not direct how covered entities should use funds they would have otherwise spent on acquiring drugs at market prices, and covered entities can simply pocket the "spread" between the lower 340B price and the higher commercial-insurance or government-program reimbursement rate. This structure has made improper 340B practices endemic as covered entities pursue the spread while for-profit, third-party commercial pharmacies and pharmacy benefit managers woo covered entities with the promise of identifying the maximum amount of supposedly 340B eligible claims in return for a cut of the action—an arrangement that incentivizes claiming unauthorized 340B price concessions. In the face of this increasing fraud and abuse, BMS decided it had to act.

BMS's intended "cash-rebate model" is authorized by the 340B statute and is in step with prior Department of Health and Human Services (HHS) practice endorsing both the AIDS Drug Assistance Program (ADAP) rebate model and the "product-replenishment model" overwhelmingly used by covered entities. It also will ensure BMS's products are not subject to statutorily forbidden duplicate discounts under 340B and the MDRP. And it will allow BMS to meet its obligation under a separate Inflation Reduction Act (IRA) provision that requires a manufacturer with a product subject to that statute's "maximum fair price" (MFP) requirement to charge the lower of the MFP or the 340B ceiling price on a prescription, but not be compelled to provide both.

When BMS sought to exercise its statutory right to implement a cash-rebate model, the Health Resources and Services Administration (HRSA), an HHS subagency, claimed that BMS could not launch the model without HRSA's preapproval. And HRSA threatened other manufacturers who announced similar cash-rebate models with termination from the 340B Program—rendering the manufacturer's products ineligible for reimbursement by Medicaid and Medicare Part B—and crushing civil monetary penalties if they did not obey HRSA's claim of preapproval power. Those actions are not just ham-fisted; they violate the Administrative Procedure Act (APA) for three distinct reasons.

First, HHS cannot wall off one of the 340B statute's available means of providing 340B pricing for eligible prescriptions. Congress gave manufacturers the option between discounts and rebates, and the agency cannot read one out of the statute without violating the APA.

Second, HHS's refusal to approve BMS's cash-rebate model is arbitrary and capricious. HRSA has countenanced cash rebates for ADAPs and the current product-replenishment model for all covered entities—both rebate models—for years. The agency cannot halt BMS's cash-

rebate model without unlawfully treating like cases differently. HRSA's position also disregards the compelling programmatic-integrity rationale for adopting the cash-rebate model, denies BMS the only feasible means of preventing unlawful MFP-340B duplication, and frustrates the commonsense program-integrity benefits the cash-rebate model offers. At every turn, the administrative record reveals HRSA's reasoning to be both inadequate and inadequately explained. It is arbitrary for these reasons as well.

Finally, HRSA's decision is illogical and runs afoul of substantive-due-process principles that guard against irrational governmental action. HHS cannot tell manufacturers like BMS they must devise their own way to avoid 340B-MFP duplicate discounts and then tell manufacturers they cannot use the cash-rebate model—the only way manufacturers have to avoid 340B-MFP duplicate discounts.

HRSA's decision to block BMS's cash-rebate model is unlawful and should be set aside.

STATEMENT OF FACTS

I. THE FEDERAL 340B PROGRAM

A. The Statutory Framework

Before the 340B program, manufacturers voluntarily sold reduced-price medicines to the Department of Veterans Affairs and certain other providers, such as rural hospitals and community health centers. But when Congress enacted the federal MDRP in 1990, it inadvertently interfered with that practice. *See* H.R. Rep. No. 102-384(II), *9–10 (1992). The MDRP requires drug manufacturers to offer Medicaid discounts that match the lowest price they offer to other buyers—meaning that if a manufacturer were to continue to sell discounted medicines to the VA and other providers, it could drastically increase the rebates owed to Medicaid. The MDRP thus effectively disincentivized manufacturers from continuing to offer reduced-price medicines to entities serving disadvantaged populations.

Congress sought to remedy that disincentive with the 340B program. Congress created the 340B Program under the Veterans Health Care Act of 1992, codified as Section 340B of the Public Health Service Act, *see* 42 U.S.C. § 256b,[1] and later amended.[2] The program works by conditioning federal reimbursement under Medicaid and Medicare Part B on the HHS Secretary's "enter[ing] into an agreement with [the] manufacturer." 42 U.S.C. § 256b(a)(1). The agreement, known as a Pharmaceutical Pricing Agreement, or PPA, "incorporate[s] statutory obligations and record[s] the manufacturers' agreement to abide by them." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 117–118 (2011); AR 202.

Each PPA provides that the manufacturer "shall offer" its medicines to each covered entity at or below the applicable "ceiling price." 42 U.S.C. § 256b(a)(1); AR 43–44, 46–47. A manufacturer satisfies that "shall offer" requirement so long as it makes an offer to sell its medicines to covered entities at or below the ceiling price, including with reasonable conditions that still allow covered entities to access the price. *See, e.g.*, *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 459–461 (D.C. Cir. 2024) (rejecting HRSA's attempt to stop manufacturers from placing "reasonable conditions" on delivery); *see also Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 701, 706 (3d Cir. 2023) (upholding a manufacturer requirement that covered entities provide claims data).

The 340B statute contemplates that 340B prices may be effectuated by either a front-end "discount" or back-end "rebate." Specifically, the statute requires manufacturers to "enter into an agreement" (a PPA) "under which the amount required to be paid (taking into account any rebate

[1] *See also* Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (1992).

[2] Pub. L. No. 103-43, § 2008, 107 Stat. 122, 212 (1993); Pub. L. No. 111-148, §§ 2501, 7102, 124 Stat. 119, 309, 709 (2010); Pub. L. No. 111-152, § 2302, 124 Stat. 1029, 1082 (2010); Pub. L. No. 111-309, § 204, 124 Stat. 3285, 3289 (2010).

or discount, as provided by the Secretary), to the manufacturer for covered outpatient drugs . . . does not exceed" the ceiling price. 42 U.S.C. § 256b(a)(1). BMS's PPA, like every manufacturer's PPA, makes no mention of "rebate[s] or discount[s]"; it simply states that the "[m]anufacturer shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." AR 47.

Congress created statutory guardrails to help "assure the integrity of the drug price limitation program." H.R. Rep. No. 102-384(II), *9–10 (1992). To that end, the 340B statute limits 340B pricing in important respects. For example, if 340B pricing is given on a unit, a covered entity cannot also receive a rebate under the MDRP for that unit. *See* 42 U.S.C. § 256b(a)(5)(A). The 340B statute also includes procedures intended to help police unlawful duplication and diversion. Congress directed HHS to create an Administrative Dispute Resolution (ADR) mechanism to address these abuses, 42 U.S.C. § 256b(d)(3)(A), and HHS has done so, *see* 340B Drug Pricing Program, 89 Fed. Reg. 28,643 (Apr. 19, 2024); 42 C.F.R. § 10.21(a). But before a manufacturer can access ADR proceedings, it must first audit a covered entity's records that "directly pertain to the entity's compliance" with the prohibitions on duplication and diversion. 42 U.S.C. § 256b(a)(5)(C).

HRSA, however, has locked manufacturers' access to audits behind a requirement not found in the statute. HRSA requires manufacturers to first show "reasonable cause" for initiating an audit. Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406, 65,410 (Dec. 12, 1996). To do that, HRSA demands "sufficient facts and evidence in support of the belief." *See id.* So if a manufacturer lacks hard evidence that a covered entity has duplicated

discounts, HRSA's procedures put it in a Catch-22: To get the evidence, the manufacturer must conduct an audit, but it cannot conduct an audit until it has the evidence.[3]

B. The Product-Replenishment Model and Its Consequences

The current method for effectuating 340B prices is far from intuitive. Covered entities have created a system of *in-kind* or *product* rebates, often called the "product-replenishment model." Covered entities pay the market price for medicine up front, then later "replenish" that product at the 340B price after identifying enough prescriptions to 340B patients. *See* Declaration of Justin McCarthy (McCarthy Decl.) ¶¶ 8–9. Covered entities do not even attempt to distinguish between 340B inventory and non-340B inventory. *See id.* That commingling conceals which inventory is subject to the anti-duplication and anti-diversion provisions of the 340B statute, inevitably causing 340B-priced medicines to be diverted to non-340B patients or submitted to Medicaid for rebates.

1. Creation of the Product-Replenishment Model

That has not always been so. At the 340B Program's outset, most covered entities used a physical-inventory model. Under that model, covered entities physically segregated 340B-priced medicines from commercial priced medicines and determined whether a prescription was 340B-eligible *before* it was dispensed. *See* 340B Health, *Key Terms*, *available at* https://www.340bhealth.org/members/340b-program/key-terms; HHS Off. of Inspector Gen. (OIG), *Contract Pharmacy Arrangements in the 340B Program* 5 (Feb. 4, 2014) (Contract Pharmacy Arrangements), *available at* https://oig.hhs.gov/documents/evaluation/2914/OEI-05-13-00431-Complete Report.pdf. If a unit met the criteria to be purchased at the 340B price, the

[3] BMS reserves all rights to challenge this HRSA requirement as arbitrary, capricious, contrary to law, and in excess of HRSA's statutory authority. But that challenge is outside the scope of this case.

covered entity dispensed a 340B-priced unit; if not, the covered entity dispensed a commercially purchased unit. That segregated-inventory system offered all parties some measure of confidence that a 340B-priced unit would be dispensed only when a prescription is 340B-eligible.

Covered entities came to dislike the inconvenience of physically segregating inventory as they turned their efforts to expansion through the contract-pharmacy model. The product-replenishment model came about as a solution. It rests on an elaborate accounting fiction: (1) a "full package" of medicine is purchased at market price; (2) that medicine is dispensed, often in smaller quantities; (3) sometime later, covered entities or their vendors assess whether prescriptions were 340B-eligible; (4) after purporting to fill enough eligible prescriptions to equal a full package, a "replenishment" package is purchased at the 340B price; (5) the 340B-priced replenishment package is placed in general inventory; (6) the replenishment medicine is dispensed—regardless of whether the person filling the prescription is a patient of the 340B provider; and (7) the cycle begins anew. *See generally* McCarthy Decl. ¶¶ 8–9.

A defining characteristic of the product-replenishment model's accounting fiction is that covered entities neither determine whether a unit is 340B-eligible before dispensing it nor establish which unit is "340B" for purposes of the covered entity's compliance obligations. Regardless of whether a package of medicine is purchased at a 340B or non-340B price, it is placed in neutral inventory, where units from that package may be dispensed *regardless* of whether a prescription is 340B-eligible. McCarthy Decl. ¶ 9. Only after those units are dispensed do covered entities or their vendors "attempt to discern" whether individual units were actually eligible for the 340B price. *Novartis Pharms. Corp.*, 102 F.4th at 457. Thus, a unit may be treated as a commercial unit for dispensing purposes, but as a 340B unit for pricing purposes.

That bifurcated system facilitates straightforward violations of the 340B statute's duplication and diversion prohibitions by treating a medicine's 340B status as transferrable and divorced from the price at which is it sold. Medicine starts out the journey as *commercial* (freeing the unit to be dispensed to anyone), then becomes *340B* (to generate a replenishment claim), and that 340B status is then *transferred* from the dispensed medicine to the replenishment medicine (so that the latter can be purchased, in theory, at the 340B price), but the covered entity then deems the replenishment medicine commercial so that it can be dispensed to anyone. That constant yo-yoing of 340B status nullifies the statute's duplication and diversion prohibitions. Under the product-replenishment regime, covered entities necessarily purchase medicine at a 340B price and then "resell or otherwise transfer the drug" to non-340B-eligible individuals. 42 U.S.C. § 256b(a)(5)(B). Moreover, the shifting nature of which units are "340B" makes tracking duplication virtually impossible. *See* Contract Pharmacy Arrangements at 1–2.

HHS nevertheless has acceded to the product-replenishment model's widespread adoption, characterizing the model as simple "inventory-accounting." HHS Off. of the Gen. Couns., *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* 6 & n.6 (Dec. 30, 2020) (Contract Pharmacies Opinion), *available at* https://perma.cc/L7W2-H597. Notably, HRSA never purported to *preapprove* the product-replenishment model's use, including its in-kind rebate attributes. Covered entities created it without agency consent—or manufacturer consent.

2. Third Parties' Involvement in the Product-Replenishment Model

Not all covered entities dispense covered outpatient drugs in-house. HRSA has permitted covered entities to use "contract pharmacies": for-profit commercial pharmacies that "dispens[e] 340B-purchased drugs on behalf of a covered entity." Contract Pharmacy Arrangements 4. For-profit contract pharmacies administer the product-replenishment model in much the same way as covered entities.

Some covered entities and contract pharmacies bring in for-profit third-party administrators to manage the product-replenishment model. Those administrators, too, are in it for the money. As the D.C. Circuit has explained, third-party administrators "often receive a larger fee for every prescription deemed eligible for the discount." *Novartis Pharms. Corp.*, 102 F.4th at 457. For that reason, covered entities, contract pharmacies, and third-party administrators alike have "a financial incentive to catalog as many prescriptions as possible as eligible for the discount." *Id.* at 457–458. The players all "divvy up the spread between the discounted price and the higher insurance reimbursement rate." *Id.* at 457.

The methods by which covered entities, pharmacies, and administrators retrospectively "catalog" those supposedly 340B-eligible prescriptions, *id.*, are shrouded in secrecy. Contract pharmacies and third-party administrators use black-box algorithms to determine which prior prescription fills may have been 340B-eligible. And third-party administrators market their prowess in identifying as many supposedly 340B-eligible transactions as possible. *See* Sayeh Nikpay & Lucas Halvorson, *Growing Administrative Complexity in the 340B Program and the Rise of Third-Party Administrators*, 1 Health Affs. Scholar 1, 3–4 (2023). To "maximiz[e] the revenue potential of 340B discounts," third-party administrators review prescription data and "identify opportunities" for generating more 340B claims. *Id.* The proprietary algorithms used to perform that task run various profitability scenarios, revealing the most desirable and allowing "for-profit pharmacies to influence which prescriptions are classified as 340B." Aaron Vandervelde et al., Berkeley Rsch. Grp., *For-Profit Pharmacy Participation in the 340B Program* 8 (Oct. 2020), *available at* https://tinyurl.com/4e3eheu4; *see also* Neal Masia, Ph.D., Alliance for Integrity & Reform, *340B Drug Pricing Program: Analysis Reveals $40 Billion in Profits in 2019*, at 2, *available at* https://tinyurl.com/msj74879.

The predictable result: The algorithms sweep in customers who are not "patients" of the covered entity. *See, e.g.*, Government Accountability Office (GAO), *GAO-11-836, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 28 (Sept. 2011), *available at* https://www.gao.gov/assets/d11836.pdf. Those algorithms also can end up tagging one individual as a "patient" of multiple covered entities, such that more than one covered entity claims a given contract pharmacy prescription as their own, creating duplicative 340B discounts for the same prescription and dispense.[4]

Identifying purported 340B-eligible transactions thus has become big business. A handful of massive for-profit pharmacy chains and pharmacy benefit managers now dominates the contract-pharmacy industry.[5] Those entities receive a startling share of the pie: About 16 percent of *all* 340B "revenue" currently goes to for-profit third parties.[6] And third parties are not shy about their dependence on this largesse. In its 2023 10K, for instance, Walgreens admitted that changes to contract-pharmacy arrangements under the 340B program "could . . . significantly reduce [its] profitability."[7] CVS likewise warned investors that "a reduction in the use of the Company's administrative services by Covered Entities . . . could materially and adversely affect the Company."[8]

---

[4] *See* Adam J. Fein, Drug Channels, *EXCLUSIVE: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340BContract Pharmacy Market* (July 11, 2023), *available at* https://bit.ly/3ZH23yG.

[5] *Id.*

[6] Minnesota Dep't of Health, *340B Covered Entity Report* 9 (Nov. 25, 2024), *available at* https://www.health.state.mn.us/data/340b/docs/2024report.pdf.

[7] Walgreens Boots Alliance, *2023 Annual Report* 33 (Oct. 12, 2023), *available at* https://investor.walgreensbootsalliance.com/static-files/43e9965c-4947-4673-aa3f-201a78a3d202.

[8] CVS Health, *2023 Annual Report* 26 (Feb. 7, 2024), *available at* https://s2.q4cdn.com/447711729/files/doc_financials/2023/ar/CVS-Health-2023-Annual-Report.pdf.

This arbitrage revenue does not necessarily make it into *patients'* pockets. *See* IQVIA, *supra*, at 3. As covered entities themselves have emphasized, "the 340B program does not require passing 340B discounts on to patients." Amicus Brief of 340B Health, *Genesis Healthcare v. Becerra*, No. 4:19-CV-1531 (D.S.C. Sept. 20, 2023), ECF No. 124-2 at 2 (340B Health Brief). Covered entities use the profits they make on 340B drug sales to fund "a wide range of activities." *Id.* at 3.

The financial incentives created by the product-replenishment model have warped the 340B Program beyond recognition. The program's original mission was to support the care of uninsured, low-income patients.[9] But dispensing 340B-priced medicine to *uninsured* patients deprives covered entities and their for-profit partners of any spread to divvy up because that spread comes from the difference between the 340B price reduction and "reimburse[ments] by insurers . . . at the non-discounted price of the drug." 340B Health Brief at 2; *see, e.g.*, Katie Thomas & Jessica Silver-Greenberg, *How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, N.Y. Times (Sept. 27, 2022), *available at* https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html (reporting that "[t]hanks to 340B," a hospital "can buy a vial of Keytruda, a cancer drug, at the discounted price of $3,444," and then "charge[ ] the private insurer Blue Cross Blue Shield more than seven times that price—$25,425"). So some covered entities now outright refuse to "offer the 340B price to uninsured patients in any of their contract pharmacy arrangements." Contract Pharmacy Arrangements at 14.

[9] IQVIA, *Unintended Consequences: How the Affordable Care Act Helped Grow the 340B Program* (Aug. 30, 2024) *available at* https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2024/unintended-consequences-howthe-affordable-care-act-helped-grow-the-340b-program.pdf ("From 2013 to 2021, while the size of the vulnerable population almost halved, 340B drug discount revenue grew by 374%.").

Despite that system's plain potential for spawning incorrect and duplicate discounts, HRSA conducts only token supervision. GAO has long "identified several areas of weakness in HRSA's oversight processes that impede its ability to ensure that duplicate discounts are prevented or remedied." GAO, *GAO-18-480, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 23 (June 2018) (2018 GAO Report), *available at* https://www.gao.gov/assets/d18480.pdf. 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 fails to create "reasonable assurance" that duplicate discounts can be avoided, leaving drug manufacturers "at risk." *Id.* at 24–25. Worse, HRSA does not even try to "assess for the potential for duplicate discounts in Medicaid managed care," which is "particularly problematic" because that space sees the majority of Medicaid drug spending and, likely, the majority of duplicate discounts. *Id.* at 25–26. HRSA recently doubled down on this no-managed-care-audit policy, even though it conceded that utilization of Medicaid managed care can result in prohibited discount duplication. *See* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 89 Fed. Reg. 28,634, 28,649 (Apr. 19, 2024).

3. 340B Program Abuse Under the Product-Replenishment Model

Unsurprisingly, the combined result of distorted financial incentives and lack of government oversight is a 340B Program overrun with abuse. And the Court need not take BMS's word for it; the federal government has confirmed that finding repeatedly. *E.g.*, 2018 GAO Report at 15–16 (noting that "72 percent of the covered entities audited in fiscal years 2012 through 2017 had one or more findings of noncompliance"); House Energy & Com. Comm., *Review of the 340B Drug Pricing Program* 36 (Jan. 10, 2018) (340B Review) (describing "discount errors" as "likely" and "duplicate discounts" as "quite common"); GAO, *GAO-20-212, Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* 25–27 (Jan. 2020) (2020 GAO

Report) (explaining that even identified instances of duplicate 340B-Medicare managed care discounts sometimes go unremedied); *see also* HHS OIG, *State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates* 10–13 (June 2016), *available at* https://oig.hhs.gov/documents/evaluation/2918/OEI-05-14-00430-Complete%20Report.pdf, (detailing how Medicaid managed-care claims can "result[ ] in duplicate discounts").

The potential for abuse intensified in 2010, when the Affordable Care Act expanded the MDRP to include Medicaid managed care organizations. *See* Pub. L. No. 111-148, § 2501, 124 Stat. 119, 308 (2010). That expansion substantially increased the potential for illegal Medicaid-340B duplicates because Medicaid managed care accounts for most Medicaid utilization. 2020 GAO Report at 1. And HRSA's failure to police duplication in Medicaid managed care means "[t]he volume of duplicate discounts . . . may be far greater than has been previously realized." 340B Review at 37.

Tellingly, expansion of the MDRP coincided with explosions of both contract-pharmacy arrangements and of Medicaid rebates. Between 2010 and 2019, the number of contract pharmacies increased from about 1,300 to about 23,000. 2020 GAO Report at 2. GAO has tied that trend to an "increase[ ]" in "the potential for duplicate discounts." *See id.* at 2. HHS OIG, too, has concluded that the proliferation of these relationships "create[s] complications in preventing duplicate discounts." Contract Pharmacy Arrangements at 2. The data are consistent with those conclusions. Total Medicaid rebates rocketed from about $15 billion in 2011 to over $36 billion by 2018, and then to about $42.5 billion by 2021. 2020 GAO Report at 2; Medicaid & CHIP Payment & Access Comm'n, *High-Cost Drugs and the Medicaid Program: MACPAC Evidence and Recommendations* (Feb. 2024) (MACPAC Report), *available at*

https://www.macpac.gov/wp-content/uploads/2024/02/Policy-in-Brief-High-Cost-Drugs-FINAL-2.pdf.

Government audits—even limited as they are—consistently find systematic violations of the 340B statute's prohibitions on duplication and diversion. *See, e.g.*, HRSA, *Audit Results of Covered Entities*, *available at* https://www.hrsa.gov/opa/program-integrity. From just 2012 to 2019, HHS audits revealed over 1,500 instances of 340B program noncompliance, including 429 instances of duplication with the MDRP, 546 instances of diversion, and 561 instances of other violations of eligibility requirements. GAO, *GAO-21-107, HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements* 14 (Dec. 2020), *available at* https://www.gao.gov/assets/gao-21-107.pdf.

Lack of access to information is at the root of many of these widespread statutory violations. For example, an HHS audit revealed that a "covered entity and its off-site outpatient facilities did not accurately appear" on HHS's 340B Medicaid Exclusion File, which HHS designed "to prevent duplicate discounts by notifying states and manufacturers which drug claims are not eligible for Medicaid rebates." 340B Review at 36–37. GAO has reached the same conclusion. In discussing covered entities' self-reported program violations, it explained that "HRSA does not know if covered entities have effectively identified the full extent of noncompliance." GAO, *GAO-23-106095, 340B Drug Discount Program: Information About Hospitals That Received an Eligibility Exception as a Result of COVID-19*, at 20 n.32 (May 11, 2023), *available at* https://www.gao.gov/assets/gao-23-106095.pdf. And self-reported violations are likely only the tip of the iceberg.

In fact, it is estimated that three-to-five percent of *all* Medicaid rebates now duplicate 340B pricing. Ashwin Mundra, *Drug Channels, The 340B Noncompliance Data Gap Leaves Drug*

Manufacturers in the Dark (Mar. 18, 2022), *available at* https://www.drugchannels.net/2022/03/the-340b-noncompliancedata-gap-leaves.html. In 2020 alone, that amounted to between *$1.3 billion and $2.1 billion* in illegal duplicates. *Id.* And the amount of duplication is likely much higher today because 340B purchases nearly doubled between 2020 and 2023, rising from $38 billion to $66 billion. Adam J. Fein, Drug Channels, *The 340B Program Reached $66 Billion in 2023—Up 23% vs. 2022: Analyzing the Numbers and HRSA's Curious Action*s (Oct. 22, 2024), *available at* https://tinyurl.com/37puawpr.

These trends show no signs of stopping, especially given the "[l]imitations in federal oversight" that "impede CMS's and HRSA's ability to ensure compliance with the prohibition on duplicate discounts." 2020 GAO Report at 27. HRSA's oversight failures are so severe as to "compromise[ ] the integrity of the 340B Program." *See id.* Drug manufacturers are on their own to stem the tide.

4. Increased Potential For Abuse After the Inflation Reduction Act

340B duplication is now poised to worsen, thanks to two aspects of the recently enacted Inflation Reduction Act (IRA). *First*, the IRA created the "Drug Price Negotiation Program," which empowers HHS to compel manufacturers into "agreements" for the government to set the prices at which Medicare units of certain medicines will be purchased. *Second*, the IRA created Medicare Part B and Part D inflation-rebate programs, under which manufacturers must pay Medicare rebates on medicines covered under Parts B and D if their prices rise faster than the rate of inflation. Both IRA programs impact manufacturers' 340B obligations by creating a further need for accurate information to avoid duplication.

The Drug Price Negotiation Program directs the HHS Secretary to "enter into agreements with manufacturers of selected [Medicare Part B and Part D] drugs," under which the Secretary and the manufacturer will be compelled to "negotiate" a "maximum fair price" (MFP) for the

selected drug. 42 U.S.C. § 1320f-2(a). The manufacturer must then "provide access to such price" with respect to eligible individuals. *Id.* § 1320f-2(a)(1). Recognizing the overlap between discounting obligations under the Drug Price Negotiation Program and those under the 340B program, the IRA also provides that manufacturers must offer only the lower of the MFP or the 340B ceiling price—not both—if a prescription is subject to both reduced prices. *Id.* § 1320f-2(d). CMS reiterates this obligation in its current guidance, instructing that "manufacturers must ensure that the appropriate price concession is honored, consistent with their obligations under [the IRA], and inclusive of their agreements under section 340B(a)(1)."[10] That is no small task. CMS gives manufacturers only 14 days to effectuate the MFP by paying a rebate. CMS 2027 IRA Guidance at 196.

The Drug Price Negotiation Program lacks any plausible mechanism for avoiding duplicate discounts. For its part, CMS has disclaimed responsibility entirely, directing manufacturers to figure out some de-duplication mechanism on their own. CMS 2027 IRA Guidance at 54–56. CMS acknowledges that a manufacturer may decline to pay an MFP rebate on account of duplication, but the manufacturer must somehow "provide documentation demonstrating the claim was 340B-eligible." *See id.* at 230. Under the product-replenishment model, manufacturers have no way of doing so; within 14 days, a covered entity often will not even have purported to identify a claim as 340B-eligible for its own purposes, and the covered entity provides no data to support its replenishment claims in any event. Worse still, neither the Drug Price Negotiation Program

[10] 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 230 (Oct. 2, 2024) (CMS 2027 IRA Guidance), *available at* https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

nor the 340B program provides manufacturers the right to audit covered entities to ensure they are not submitting unlawful duplicate claims under the IRA.

The consequences of failing to make the MFP available are severe: A manufacturer can be subject to civil monetary penalties "equal to ten times the amount" of the overcharge. 42 U.S.C. § 1320f-6(a). Under the current 340B product-replenishment system—where 340B product rebate claims are often not submitted to the manufacturers for weeks, if not months, with no accompanying data to identify whether that claim is also subject to the MFP—BMS will have to pay an MFP rebate and then, when the 340B product replenishment order comes in, pay that product rebate as well. The result thwarts the IRA's nonduplication protection for manufacturers. *Id.* § 1320f-2(d).

Medicare Part B and Part D inflation rebates lack the same fundamental protections for manufacturers. Under the applicable Part D statute, medicines subject to a 340B discount will need to be "exclude[d]" from the inflation rebate calculation starting in 2026. 42 U.S.C. § 1395w-114b(b)(1)(B). Although manufacturers will face civil monetary penalties if they fail to timely pay the appropriate inflation rebate, *id.* § 1320f-6(c), CMS has no plan to fulfill its statutory obligation to exclude 340B units from its Part D inflation rebate claims, as it acknowledges. Medicare and Medicaid Programs, 89 Fed. Reg. 97,710, 98,292–93 (Dec. 9, 2024). Nor has CMS provided for any type of dispute-resolution process or other mechanism to help ensure compliance with the duplicate-discount prohibition for either Part B or Part D drugs. *See id.* at 98,248–49 (declining to conduct audits to ensure Part B claims are accurate); *id.* at 98,306 (citing "administrative burdens" in declining to provide "additional reporting" for "Part D rebatable drugs"). The government has acknowledged that it may not bill inflation rebates to manufacturers

on 340B-priced units. But the government currently has no way to identify those prescriptions—and neither will manufacturers.

This problem is not a theoretical one for BMS. HHS selected BMS's blood-clot-treatment drug Eliquis® for the Drug Price Negotiation Program and imposed an MFP on it beginning on January 1, 2026. CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026*, at 2 (Aug. 2024), *available at* https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year2026.pdf; *see also* AR 330. BMS must therefore provide CMS with a written "plan for making the MFP available" for Eliquis, called an MFP effectuation plan, by September 1, 2025. CMS 2027 IRA Guidance at 285; AR 330. That plan must ensure the nonduplication provision's obligations and protections are both effectuated. AR 327–329.

II. BMS'S SOLUTION AND HRSA'S RESPONSE

A. The Solution: A Cash-Rebate Model

As these problems worsened with no end in sight, BMS searched for its own solution to the broken 340B program, landing on a cash-rebate model. AR 325–327, AR 339. As the name suggests, BMS's cash-rebate model would give *cash* to covered entities instead of the current replenishments of *product*. AR 318. Like the product-replenishment model, the cash-rebate model will function as a rebate: an after-purchase true-up to a price at or below the statutory ceiling price. But the cash-rebate model will accomplish that goal faster, more directly, and more transparently through data parity, thereby preserving—or even improving—covered entities' cash flow. AR 317–318, AR 329–330.

Under the cash-rebate model, BMS would make 340B prices available to all covered entities, beginning with Eliquis, through one centralized system. AR 330. Under BMS's model, 340B providers will dispense medicine and send readily available information to the platform to

confirm 340B eligibility; BMS then will promptly pay cash to the 340B providers. AR 330. That's it. This ensures a consistent and reliable cash flow to 340B providers and establishes a mechanism for identifying and preventing duplicate discounts, all while complying with BMS's statutory obligation. AR 317–318, AR 329–330, AR 338–339. Indeed, the cash-rebate model is the primary commercial model used by manufacturers with their non-340B customers where eligibility for a reduced price is not determined until after the product is purchased. McCarthy Decl. ¶ 24.

A cash-rebate model has successfully operated for decades for a type of covered entity called AIDS Drug Assistance Programs, or ADAPs. AR 11–14, AR 323. An ADAP is a state- or territory-sponsored payor that "provides FDA-approved medications to low-income people with HIV." HRSA, *Part B: Aids Drug Assistance Program (ADAP)* (last updated Dec. 2024), *available at* https://ryanwhite.hrsa.gov/about/parts-and-initiatives/part-b-adap. Under the ADAP cash-rebate model, after an initial market-price purchase, manufacturers give ADAPs cash, in amounts that "equal or exceed the discount provided by the statutory ceiling price," just as BMS is now proposing to do for all covered entities. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Rebate Option, 62 Fed. Reg. 45,823, 45,824 (Aug. 29, 1997) (Rebate Notice).

HRSA has not objected to the ADAP cash-rebate arrangements. Nor has it asserted that such arrangements required its preapproval. Instead, after HRSA noticed the existing prevalence (and, presumably, the desirability) of these arrangements, the agency proposed to formally "recognize[ ]" the model as a legitimate "method of accessing the 340B program." Rebate Notice, 62 Fed. Reg. at 45,824. Then, after a public-comment period, HRSA "recognize[d] an ADAP rebate option" as "consistent with the section 340B rebate program" without purporting to impose "in-depth implementation strategies." AR 12 (Notice Regarding Section 602 of the Veterans Health Care Act of 1992—Rebate Option, 63 Fed. Reg. 35,239, 35,240 (June 29, 1998)) (Rebate

Final Notice). The agency simply recommended that ADAPs receiving cash rebates follow "[s]tandard business practices." *Id.*

B. The Response: A Nuclear Threat

In October 2024, BMS notified HRSA of its proposed cash-rebate-model solution. AR 306–320. BMS introduced the model and requested a meeting with the agency to discuss the model in more detail. AR 306–307. BMS explained that it planned to pilot the model in early 2025. AR 311, AR 317.

BMS and HRSA met on October 22 to discuss the cash-rebate model. AR 317. Soon after, BMS followed up with a letter providing further details and asking the agency to acknowledge BMS's right to implement the model. AR 317–320. In the letter and accompanying documents, BMS explained that the agency has long permitted 340B rebate models without preapproval, AR 323–325; recounted the well-documented abuses within the 340B Program, AR 325–327; outlined the statutory intersection with the IRA's Drug Price Negotiation Program, AR 327–329; and described in detail BMS's intended rebate model and its implementation framework, including the legal basis permitting the model, AR 329–334. BMS requested a response by November 4, 2024. AR 317.

Instead of embracing or even engaging with BMS's solution, HRSA reflexively shut it down. In a November 4, 2024 letter, the agency claimed that offering the 340B price using a cash-rebate model would "require [its] approval" in advance. AR 342; ECF No. 1-1. The letter went on: "To date, the Secretary has not provided for such a rebate model. 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 BMS has proposed." AR 342. Parroting language in letters sent to other manufacturers, *see* AR 66, AR 292, HRSA instead asked

BMS several further questions about the cash-rebate model without indicating when or whether the agency would consider purporting to "approve" the model's use. AR 342–344.

On November 12, 2024, and in the interest of continuing to work collaboratively with HHS, BMS fully responded to HRSA's request for additional information. AR 345. In doing so, BMS reiterated that HRSA does not have the power to require preapproval of a rebate model. BMS also asked whether there was *any* rebate model that HRSA would approve and stated that, if HRSA did not respond by November 27, BMS would understand the agency to maintain its position that *no* rebate model was permissible. *See* AR 345 (attaching Nov. 11, 2024 letter to HRSA).

HRSA responded to BMS's letter on November 21, 2024, but declined to revisit its disapproval. AR 345. HRSA repeated that as it had "previously stated," if BMS proceeded with "implementing a rebate proposal without Secretarial approval," BMS "would violate Section 340B(a)(1) of the Public Health Service Act." AR 345. HRSA's response was consistent with its past position that the agency "only recognizes a rebate option for the State AIDS Drug Assistance Programs that receive assistance under Title XXVI of the PHS Act" because the agency "agree[d]" that it should "not consider any further expansion to other categories of entities." 63 Fed. Reg. at 35,241–42. HRSA reaffirmed its position in a letter it sent to BMS on December 13, stating that BMS would violate the 340B statute if it proceeded with "[i]mplementing a rebate proposal without Secretarial approval." AR 347.

Around the time BMS notified HRSA of its intent to implement the model, other manufacturers, including Johnson & Johnson, had announced their intention to implement similar cash-rebate models. In response to those other manufacturers, HRSA made its position consistent and clear. In an August 14, 2024, letter to Johnson & Johnson, the agency used precisely the same language it later used in its response to BMS: "To date, the Secretary has not provided for such

rebate as proposed by J&J. 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 J&J has proposed." AR 66.

A month later, HRSA sent a second letter to Johnson & Johnson. *See* AR 202–204. That letter asserted the same purported preapproval power over Johnson & Johnson's cash-rebate plan, but this time, its letter contained a nuclear threat: If Johnson & Johnson implemented a cash-rebate model without HRSA's preapproval, the agency may terminate its PPA—and with it, the availability of federal funds under Medicaid and Medicare Part B for Johnson & Johnson's products—and assess civil monetary penalties, too. AR 203. And HRSA followed up with a *third* letter ten days later, warning Johnson & Johnson that, if it implements a cash-rebate model, HRSA "*will* begin the process" of terminating its PPA and "*will*" refer Johnson & Johnson to HHS OIG. AR 214–215 (emphases added).

HRSA's threat applies to all drug manufacturers, as the agency later made clear. After Sanofi told covered entities that it would implement a cash-rebate model, HRSA responded exactly as it had before. The agency sent Sanofi a letter asserting purported preapproval authority over Sanofi's cash-rebate model, and it threatened to terminate Sanofi's PPA and impose civil monetary penalties if Sanofi did not comply. AR 424–425. HRSA also published those letters prominently on its website. *See Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 436 (D.C. Cir. 1986); HRSA, *340B Drug Pricing Program* (last updated Jan. 2025), https://www.hrsa.gov/opa. On the same page, the agency trumpets its blanket legal position: "[I]mplementing a rebate proposal without Secretarial approval would violate Section 340B(a)(1) of the Public Health Service Act." *Id.*; *see also Pharm. Rsch. & Mfrs. of Am. v. HHS*, 138 F. Supp. 3d 31, 43–44 (D.D.C. 2015) (noting that HRSA had announced the supposed "statutory requirements" on its website) (quotation omitted).

C. The Last Resort: Lawsuits

Shortly after HRSA announced its position and threatened revocation of manufacturers' PPAs, several manufacturers sued the agency. Johnson & Johnson, Eli Lilly, and BMS all filed suit in November 2024, followed by Sanofi in December and Novartis in January. *See Johnson & Johnson Health Care Sys. Inc. v. Becerra*, No. 24-CV-3188 (D.D.C. filed Nov. 12, 2024); *Eli Lilly & Co. v. Johnson*, No. 24-CV-3220 (D.D.C. filed Nov. 14, 2024); *Sanofi-Aventis U.S. LLC v. HHS*, No. 24-CV-3496 (D.D.C. filed Dec. 16, 2024); *Novartis Pharms. Corp. v. Becerra*, No. 25-CV-117 (D.D.C. filed Jan. 15, 2025). All of the suits seek to set aside HRSA's unlawful rejection of a cash-rebate model for 340B compliance.

ARGUMENT

I. THE GOVERNING LEGAL STANDARDS

The APA requires a reviewing court to "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Agency action must be set aside when it violates a statute, *Orion Rsrvs. Ltd. P'ship v. Salazar*, 553 F.3d 697, 703 (D.C. Cir. 2009), or the agency's own regulations, *National Env't Dev. Ass'n's Clean Air Project v. EPA*, 752 F.3d 999, 1009 (D.C. Cir. 2014). Agency action is arbitrary and capricious if it treats similar cases differently without adequate explanation. *See, e.g.*, *Lone Mountain Processing, Inc. v. Sec'y of Lab.*, 709 F.3d 1161, 1164 (D.C. Cir. 2013). So too if the agency defies logic, or if the agency's decision reflects a lack of reasoned decisionmaking. *See, e.g.*, *Fox v. Clinton*, 684 F.3d 67, 80 (D.C. Cir. 2012).

This Court undertakes a "searching and careful" inquiry into the basis of the agency's decision. *Zotos Int'l, Inc. v. Young*, 830 F.2d 350, 352 (D.C. Cir. 1987). The Court "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). And although the Court may defer to an agency's

technical or scientific judgments to the extent they are consistent and reasonable, the Court does "not hear cases merely to rubber stamp agency actions." *Nat. Res. Def. Council, Inc. v. Daley*, 209 F.3d 747, 755 (D.C. Cir. 2000). The APA instead requires the Court to hold agency action unlawful unless it reaches the "independent conclusion," *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1492 (D.C. Cir. 1995), that the action was "reasonable and reasonably explained," *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

II. HRSA'S "PREAPPROVAL" REQUIREMENT IS UNLAWFUL.

A. The Statutory Text Puts Rebates and Discounts on Equal Footing.

Nothing in the 340B statute suggests a preference for either discounts or rebates. The text simply requires manufacturers to agree to charge no more than the statutory ceiling price. *See* 42 U.S.C. § 256b(a)(1). Under that agreement, "the amount required to be paid" must account for "any *rebate* or discount, as provided by the Secretary." *Id.* (emphasis added). The statute's use of the disjunctive "or" matters because it connotes a choice between two valid alternatives. *See, e.g.*, *In re Espy*, 80 F.3d 501, 505 (D.C. Cir. 1996).

The 340B statute continues to reference rebates throughout. The very next paragraph, for example, defines the statutory ceiling price, which is achieved by reducing the "average manufacturer price." *See* 42 U.S.C. § 256b(a)(2). That reduction is called the "rebate percentage." *Id.* Later, in the statute's prohibition on duplication, it again describes "discounts or rebates." *Id.* § 256b(a)(5)(A). And when Congress amended the 340B statute to improve its functionality, one of the targeted changes was a "mechanism" for reporting "rebates and other discounts" and ensuring that "such discounts or rebates" resulted in the appropriate ceiling price. *See id.* § 256b(d)(1)(B)(iv). Such persistent textual parity between rebates and other forms of achieving the ceiling price belies any suggestion that the statute disfavors rebates. "Had Congress intended

to" mandate the use of point-of-sale discounts, "it presumably would have done so expressly." *Russello v. United States*, 464 U.S. 16, 23 (1983).

B. The Statute Permits Manufacturers to Choose Between Rebates and Discounts Unless and Until HRSA Amends PPAs to "Provide[ ]" for One.

BMS's PPA makes no distinction between rebates and discounts. In fact, it does not mention discounts or rebates at all. It provides only that BMS "shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." AR 47 § 2. Like the statute, BMS's PPA does not specify a mechanism for doing so. *See id.* That is unsurprising because, in practice, PPAs have "simply incorporate[d] statutory obligations and record[ed] the manufacturers' agreement to abide by them." *Astra USA*, 563 U.S. at 118. And because there is no express constraint, manufacturers may choose how to offer 340B prices. *Novartis Pharms. Corp.*, 102 F.4th at 460; *see also Sanofi*, 58 F.4th at 707 ("Legal duties do not spring from silence.").

HRSA has nevertheless attempted to deny BMS the freedom to implement the ceiling price using one of the methods the statute expressly contemplates. The agency's position violates the fundamental precept that " 'a matter not covered is to be treated as not covered'—a principle 'so obvious that it seems absurd to recite it.' " *GE Energy Power Conversion Fr. SAS, Corp. v. Outokumpu Stainless USA, LLC*, 590 U.S. 432, 440 (2020) (quoting Antonin Scalia & Bryan J. Garner, *Reading Law: The Interpretation of Legal Texts* 93 (2012)).

C. HRSA Has No Ad Hoc "Preapproval" Authority.

Perhaps recognizing the 340B statute's permissiveness, HRSA has not quite claimed that the statute outright forbids manufacturers to use a cash-rebate model. Its position instead is that manufacturers cannot do so without HRSA's *preapproval*. *See* AR 342, AR 345. HRSA apparently intends to exercise that supposed preapproval authority by ad hoc and opaque

adjudications on whatever timeline it deems convenient. *See* AR 347 (purporting to withhold approval of BMS's cash-rebate model indefinitely while considering BMS's responses to various questions).

But the 340B statute does not give HRSA that power. HRSA has repeatedly emphasized that the 340B statute mentions a role for HHS's Secretary in choosing between rebates and discounts. *See, e.g.*, AR 342 (BMS Letter); AR 202 (Johnson & Johnson Letter). Yet HRSA suggests that the agency may compel that selection by any method it likes only by ignoring the context in which the statutory reference to the Secretary occurs. The statute directs the Secretary to "enter into an agreement with each manufacturer"—that is, a PPA—"*under which* the amount required to be paid" to the manufacturer does not exceed the ceiling price. 42 U.S.C. § 256b(a)(1) (emphasis added). Thus, it is the PPA "under which" the ceiling price must account for "any rebate or discount, as provided by the Secretary." *Id.* Put differently, any restrictions on the selection of either rebates or discount must be contained in the PPA, which binds its signatories.

That conclusion also follows from "the broader context of the statute as a whole." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997). The phrase "as provided by the Secretary" occurs in the part of the statute devoted solely to establishing "requirements for agreement with Secretary." 42 U.S.C. § 256b(a) (capitalization altered). That statutory heading supplies a further "cue[ ] that Congress did not intend" to give HRSA unfettered discretion to employ case-by-case decisionmaking. *Yates v. United States*, 574 U.S. 528, 540 (2015).

HRSA thus misconstrues the statute by pointing out that it "has not provided for such a rebate model." AR 342. That is exactly backwards. Under the statute, any "providing" the Secretary intends to attempt must be done through a PPA amendment. So what matters is that

BMS's PPA contains no limit on how it may charge a rate at or below the ceiling price—or, indeed, any instructions *whatsoever* for effectuating 340B prices. *See* AR 47.

The PPA's silence in this regard is no accident. HRSA could not, of course, amend BMS's PPA to require any particular price-setting mechanism without articulating a reasoned basis for doing so. *See Doe v. Devine*, 703 F.2d 1319, 1326 (D.C. Cir. 1983) (applying the arbitrary-and-capricious standard to an agency's contracting behavior). And HRSA could not articulate any reasonable basis for enshrining the disastrous product-replenishment model as a legal requirement. Any attempt to do so would lay bare the myriad problems with that model and entangle the agency in a doomed attempt to "show that there are good reasons" for eschewing a transparent, fair solution to those problems. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)). But what HRSA cannot do explicitly for lack of rational justification, it also may not do by silently withholding preapproval, manufacturer-by-manufacturer and case-by-case.

III. HRSA'S POSITION IS ARBITRARY AND CAPRICIOUS.

HRSA's refusal to approve BMS's cash-rebate model is independently unlawful because it is arbitrary and capricious in at least five respects. *First*, the cash-rebate model already has succeeded with ADAPs, as HRSA has acknowledged, so the agency cannot prevent its implementation as to other covered entities without irrationally treating like cases differently. *Second*, the product-replenishment model and the cash-rebate model are legally indistinguishable, so HRSA cannot reasonably treat them differently. *Third*, HRSA's position fails to account for the significant policy reasons for adopting the cash-rebate model. *Fourth*, HRSA's position denies BMS the only feasible means of preventing MFP-340B duplication. *Fifth*, HRSA's position frustrates the commonsense benefits the cash-rebate model offers.

HRSA waves manufacturers away by saying simply that implementing a cash-rebate model "without Secretarial approval" would violate the 340B statute, at no point meaningfully engaging with BMS's reasoned objections to HRSA's rejection of its cash-rebate model. *See, e.g.*, AR 345. That nonresponse confirms the agency's cupboard is bare.

A. HRSA Has Offered No Cogent Reason for Treating ADAPs and Other Covered Entities Differently.

An agency's obligation to "treat like cases alike" is a "fundamental principle of administrative law." *Grayscale Invs., LLC v. SEC*, 82 F.4th 1239, 1242 (D.C. Cir. 2023). To reasonably treat two situations differently, an agency must "identify the features of" each situation "that point toward one [decision] or another" and "offer sensible distinctions between" them. *Colo. Interstate Gas Co. v. FERC*, 850 F.2d 769, 775 (D.C. Cir. 1988). The agency's distinctions must be rooted in "the relevant regulatory factors." *Grayscale Invs.*, 82 F.4th at 1245. HRSA's attempt to quash BMS's implementation of a cash-rebate model here, however, treats like cases differently in two critical ways: it allows manufacturers to use cash rebates for ADAPs and without any preapproval, but now disallows cash rebates for other types of covered entities based on an invented preapproval requirement. Those disparities have no reasonable basis, and HRSA has offered no justification for creating it.

ADAPs' participation in the 340B program via a cash-rebate model is now a "long-standing practice." 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300, 52,313 (Aug. 28, 2015). For decades, ADAPs have been able "to access 340B prices on covered outpatient drugs" by receiving "a rebate after the purchase." *Id.* HRSA has not denounced this practice as unlawful, nor did it require preapproval before manufacturers and ADAPs instituted it; HRSA instead formally *endorsed* that cash-rebate model after the fact.

Take it from HRSA itself: After considering public comments, the agency concluded that cash rebates for ADAPs are "consistent with the section 340B rebate program." Rebate Final Notice, 63 Fed. Reg. at 35,240. Such a model does not constitute an overcharge, HRSA explained, so long as the rebates "provide at least the minimum statutory discount and do not contain requirements inconsistent with section 340B and published program guidelines." *Id.* Nor do cash rebates offend the statutory text: "Section 340B has no explicit language as to whether the required reduction in price should be obtained by an initial reduction in the purchase price (i.e., a discount mechanism) or received as a required reduction in cost rebated after purchase, dispensing, and payment are completed (i.e., a rebate option)." Rebate Notice, 62 Fed. Reg. at 45,824.

Despite HRSA's approval of a cash-rebate model for ADAPs, however, it did not purport to *pre*approve that model. Nor has BMS's PPA ever contained any instruction or authorization to use a cash-rebate model for ADAPs. *See* AR 36–47. HRSA "only recognize[d] an ADAP rebate option" that preexisted its involvement. Rebate Final Notice, 63 Fed. Reg. at 35,240; *see also id.* ("ADAPs may *continue* to provide utilization data according to terms of *existing* agreements if so desired.") (emphasis added). HRSA even described preexisting methods of implementing cash rebates as "models to be emulated," and the agency elected not to "provide in-depth implementation strategies." *Id.*

HRSA's past statements directly contradict HRSA's more-recent comments on the same subject. In its first letter to Johnson & Johnson, HRSA asserted that a cash-rebate model could violate the statute because the up-front market price may temporarily exceed the statutory ceiling price. AR 202–204. HRSA's contention to Johnson & Johnson cannot be squared with the agency's prior stance that a post-purchase rebate may be paid "as a method" of furnishing "the 340B discount provided by the statutory ceiling price." Final Rebate Notice, 63 Fed. Reg.

at 35,242. Likewise, in its recent letters to BMS and other manufacturers, the agency said nothing of "recognizing" the payment of cash rebates, insisting instead upon its advance "approval of a rebate model." AR 342 (BMS Ltr.); AR 292 (Lilly Ltr.); *see also* AR 66 (J&J Ltr.); AR 425 (Sanofi Ltr.).

HRSA had it right the first time when it blessed the ADAP cash-rebate model. Worse, in retreating from that position, HRSA failed to acknowledge or explain its about-face. HRSA has not mentioned ADAPs at all, even though BMS explained in its submission that ADAPs' use of a cash-rebate model implicates precisely the same legal questions. AR 323, AR 332–333 (BMS Ltr.). That failure is fatal to HRSA's decision. "[A]n agency's unexplained departure from precedent is arbitrary and capricious," *ABM Onsite Servs.-W., Inc. v. NLRB*, 849 F.3d 1137, 1142 (D.C. Cir. 2017), and the D.C. Circuit has "never approved an agency's decision to completely ignore relevant precedent," *Jicarilla Apache Nation v. Dep't of the Interior*, 613 F.3d 1112, 1120 (D.C. Cir. 2010).

HRSA's silence means that the agency has not tried to justify its disparate treatment of ADAPs and other covered entities by identifying special features of ADAPs that warrant a cash-rebate model. At most, HRSA once alluded to that possibility by stating that it agreed with a commenter's assertion that ADAPs have "unique needs" that justify a rebate model. Rebate Final Notice, 63 Fed. Reg. at 35,241. But neither the commenter nor HRSA explained what those supposed unique needs *are*, much less how any such needs justify foreclosing an admittedly lawful model as to other covered entities. And HRSA cannot offer those distinctions now, because "*post hoc* rationalization . . . cannot support [agency] action." *Republic Airline Inc. v. DOT*, 669 F.3d 296, 302 (D.C. Cir. 2012).

In any event, ADAPs are not meaningfully different from other covered entities. HRSA's most recent guidance manual for ADAPs recognizes as much. As the manual explains, ADAPs "submit claims to drug manufacturers for rebates on medications that were purchased through a retail pharmacy network at a price higher than the 340B price." HIV/AIDS Bureau, *AIDS Drug Assistance Program (ADAP) Manual*, 42 (June 2023) (ADAP Manual), *available at* https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/resources/adap-manual.pdf. But that is exactly how other entities use the *product*-replenishment model: They purchase drugs at the market price, often through a pharmacy network, and later reconcile that purchase with the 340B ceiling price. McCarthy Decl. ¶¶ 8–9. Similarly, HRSA noted that ADAPs implement the cash-rebate model through "formal agreements with a network of retail pharmacies." ADAP Manual 42. Again, that system mimics the contract-pharmacy and third-party-administrator arrangements utilized by covered entities under the product-replenishment model. *See* McCarthy Decl. ¶¶ 8–9.

Perhaps HRSA's most-significant concession regarding ADAPs' use of the cash-rebate model is that the model works. HRSA has recommended to ADAPs that they pursue 340B rebates using "standard business practices"—conditions inherent in rebate models that HRSA thereby implicitly has recognized as lawful. *See* Rebate Final Notice, 63 Fed. Reg. at 35,239–41. HRSA has encouraged ADAPs to provide "detailed and accurate . . . initial claim data," *id.* at 35,241, and to "engage in a thorough cash flow analysis," ADAP Manual at 43. By doing so, the agency explained, ADAPs can use rebates to "ensure a continuous cash flow" and "prevent the potential for cash shortages and program service delivery disruption." ADAP Manual at 43. That guidance dispels HRSA's purported concern, expressed to Johnson & Johnson, that a cash-rebate model may cause covered entities to struggle with "higher up-front costs" for covered drugs. AR 203. HRSA did not attempt to explain why covered entities could not simply follow the same standard

business practices that have worked for ADAPs. HRSA's imposition of different rules on indistinguishable situations was unlawful. *Dillmon v. Nat'l Transp. Safety Bd.*, 588 F.3d 1085, 1091 (D.C. Cir. 2009).

B. HRSA Has Offered No Cogent Reason for Treating the Product Replenishment and Cash Rebate Models Differently.

HRSA also failed to treat like cases alike because the current product-replenishment model used by most covered entities today is also a rebate model that HRSA has never preapproved. Covered entities and their profit-seeking partners implemented the product-replenishment model without any HRSA "preapproval" whatsoever.[11] Indeed, not only did HRSA never object to the product-replenishment model's emergence, but HRSA has also acknowledged the model's prevalence as though the agency were a bystander to the whole thing. *See, e.g.*, Contract Pharmacies Opinion 6–8 & n.6. In claiming for the first time that manufacturers require the agency's blessing before using a method of honoring the 340B price, HRSA failed to "display awareness" that it had never before asserted that power. *Encino Motorcars*, 579 U.S. at 221–222 (quotation omitted). HRSA's "failure even to acknowledge its past practice[,] . . . let alone to explain its reversal of course" is prototypically "arbitrary and capricious." *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 927 (D.C. Cir. 2017). HRSA also has not attempted to explain why its preapproval is required for cash-rebate models but not product-replenishment models. Nor could it. There is no legal distinction between the two models, and the 340B statute displays no preference between various possible mechanisms for honoring the ceiling price. *Supra* pp. 24–25.

[11] *See* National Council for Prescription Drug Programs, 340B Information Exchange 12 (July 2011), *available at* https://www.ncpdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference-Guide_v1-0.pdf (describing the model as something covered entities "may elect to utilize"). BMS's PPA does not instruct it to offer product replenishments to covered entities, and HRSA has not claimed otherwise. *See* AR 47 § 2; AR 342–345 (BMS Letter).

HRSA has likewise failed to distinguish factually between the product-replenishment model and the cash-rebate model. The core problem for the agency's position is that both models involve rebates. In the product-replenishment model, a covered entity must first pay the market price for covered outpatient medicines. *See* McCarthy Decl. ¶ 9. Only following the initial purchase at the market price may a covered entity replenish the dispensed product at the 340B price. *Id.* ¶¶ 8–9. In fact, covered entities' agents often do not even "*attempt* to discern" whether a particular medicine was eligible for the 340B price until long after dispensing it. *Novartis Pharms. Corp.*, 102 F.4th at 457 (emphasis added). And only after many such transactions may a covered entity or its contract pharmacy place an order for a full package to "replenish its section 340B purchases," effectuating the 340B price. *Id.* The product-replenishment model thus provides covered entities the 340B price retrospectively, after the initial purchase at the market price. That is the essential feature of a rebate. *See Rebate*, Oxford English Dictionary (3d ed. 2024 update) (a "deduction from a sum of money to be paid," especially "one given retrospectively"); *Rebate*, Cambridge Academic Content Dictionary (1st ed. 2008) ("money that is returned to you after you pay for goods or services"); *Rebate*, Merriam-Webster.com Dictionary ("a *refund* or deduction of part of a payment, price, or charge") (emphasis added); *Rebate*, Britannica.com Dictionary ("an amount of money that is paid *back* to you") (emphasis added).

Because both the cash-rebate model and the product-replenishment model rely on rebates, there are no "relevant regulatory factors" that allow HRSA to treat them differently. *See Grayscale Invs.*, 82 F.4th at 1245. The statute hints at only one possible distinction: whether the ceiling price is accomplished by a "rebate or discount." *See* 42 U.S.C. § 256b(a)(1). The two models are "functionally indistinguishable" on that ground, and HRSA has provided no reason to think

otherwise. *See Indep. Petrol. Ass'n of Am. v. Babbitt*, 92 F.3d 1248, 1260 (D.C. Cir. 1996). HRSA has therefore flouted "the very meaning of the arbitrary and capricious standard." *Id.*

C. HRSA Neither Acknowledged Nor Addressed The Benefits Of The Cash-Rebate Model.

Of the several ways the cash-rebate model would help restore integrity to the 340B program, two merit particular consideration: (1) the cash-rebate model would help prevent duplicate discounts and rebates—facilitating compliance with important statutory prohibitions the product-replenishment model has thwarted; and (2) the cash-rebate model would enable BMS to meaningfully participate in the statutory audit and ADR processes. But HRSA disregarded both factors in refusing to approve BMS's cash-rebate model, rendering its refusal yet again arbitrary and capricious.

An agency acts unlawfully if it "entirely fail[s] to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, (1983). An aspect of the problem is important "by definition" if Congress mandated its consideration by including it in the statute. *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1216 (D.C. Cir. 2004). And an agency may not simply purport to have considered all important aspects of the problem; it must "provide more than 'conclusory statements' to prove [it] 'considered the relevant priorities.'" *Stewart v. Azar*, 313 F. Supp. 3d 237, 259 (D.D.C. 2018) (quoting *Getty v. Fed. Savs. & Loan Ins. Corp.*, 805 F.2d 1050, 1057 (D.C. Cir. 1986)) (alterations adopted).

One of the 340B Program's basic objectives is to prevent duplicate discounts. The statute's first "requirement[ ] for covered entities" to participate in the 340B Program is to "prohibit[ ]" them from requesting "duplicate discounts or rebates" with the MDRP. 42 U.S.C. § 256b(a)(5) (capitalization altered). Congress recently reaffirmed that objective in the IRA, which directs that

manufacturers need only provide access to the lower of the 340B ceiling price and the Medicare inflation rebates the IRA imposes on manufacturers. *See* 42 U.S.C. §§ 1395w-3a(i)(3)(B)(ii)(I), 1395w-114b(b)(1)(B).

The product-replenishment model places that objective behind an insurmountable obstacle. Its critical defect is that a unit sale cannot be identified as 340B-eligible until long after it has been dispensed, and then its status as 340B-eligible may be transferred to other units, further obfuscating the audit trail. McCarthy Decl. ¶¶ 9, 16. Thus, a manufacturer cannot know that a unit sale poses a risk of duplication until it is too late to prevent it, assuming the daisy chain can even be followed through to the end.

BMS's cash-rebate model would surmount that obstacle with timely transparency. The model would align covered entities' incentives with BMS's incentives because each would have reason to identify a single unit sale as 340B-eligible as quickly as possible—covered entities to receive the 340B rebate and manufacturers to prevent duplication. The model would also give BMS the tools needed to achieve the statutory scheme's anti-duplication objective. The covered entities' readily available claims data will enable BMS to match that data with claims for rebates under the Medicaid Drug Rebate Program and with claims subject to IRA-mandated price concessions and inflation rebates. BMS can then help ensure that all stakeholders receive the price they are supposed to receive, when they are supposed to receive it.

The agency's failure to consider those benefits is especially frustrating given HHS's documented failure to solve 340B duplication problems itself. *See supra* pp. 12–15. As to the IRA's pricing programs, HHS agencies have similarly acknowledged their inability to prevent abuse. CMS has refused to "assume responsibility for nonduplication of discounts between the 340B ceiling price and" IRA price concessions. CMS 2027 IRA Guidance at 231. Nor will CMS

or its contractor "verify that a claim was or was not billed as a 340B-eligible drug" or otherwise help manufacturers identify 340B-eligible transactions. *See id.* at 54. For Medicare Part D inflation rebates, manufacturers have only CMS's faint assurances that it "plan[s] to explore" a solution to duplication problems someday. 340B Drug Pricing Program, 89 Fed. Reg. at 98,292–93.

HHS has therefore effectively thrown up its hands, leaving manufacturers to come up with some way to operationalize the statutory prohibitions on duplicative price concessions. But now that BMS has done so, HRSA has tried to foreclose BMS's solution without even acknowledging the impossible bind in which HHS agencies' abdications have put manufacturers.

The story is similar as to the 340B statute's audit and ADR procedures. Here, though, the problem is apparent on the face of the applicable statute and regulations. The product-replenishment model denies BMS access to information, locking BMS out of the statute's mechanisms for addressing the very problems HHS has refused to help solve.

If BMS suspects a covered entity has unlawfully duplicated price concessions or diverted 340B-priced units, the first step under HRSA regulations is to establish "reasonable cause" for an audit. Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406, 65,410 (Dec. 12, 1996). In other words, BMS needs some evidence that a covered entity caused a suspected violation. Under the product-replenishment model, however, BMS sometimes lacks enough information to do so because covered entities (conveniently) need not ever provide enough information for BMS to get that far.

As a result, BMS's efforts to ensure compliance often fail to launch. Without "sufficient facts and evidence in support" of "reasonable cause," there can be no audit. *Id.* Without an audit, there can be no ADR claim against a covered entity. 42 U.S.C. § 256b(d)(3)(A); 42 C.F.R.

§ 10.21(a)(2). Without an ADR claim, the 340B statute's "provision of remedies and enforcement" for its anti-duplication and anti-diversion requirements becomes a dead letter. *Contra* 42 U.S.C. § 256b(d)(3)(A).

As if that consequence were not enough, the product-replenishment model's opacity also prevents BMS from full participation in ADR proceedings initiated by others. When a covered entity brings a claim that it has been overcharged, HRSA regulations allow it to request documents or other information from a manufacturer. 42 C.F.R. § 10.22(a). A manufacturer has only 20 business days to respond, *id.* § 10.22(b), and it "is responsible for obtaining relevant information or documents" from third parties, which may be outside its control, *id.* § 10.22(c). Thus, manufacturers such as BMS operate from a doubly disadvantaged position in the ADR process. They are denied information they need to pursue their own claims, and they are saddled with an obligation to get information that is not necessarily within their grasp.

Again, the cash-rebate model's transparency would bridge those gaps. By centralizing claims data and shining a light on the bases for covered entities' requests for the 340B price, the cash-rebate model would enable all parties to vindicate their rights by using the statute's audit and ADR processes effectively. That result would not only be fairer by virtue of ensuring that price concessions are correctly paid; it would also accomplish Congress's design by effectuating its repeated prohibitions against duplication and making the statutory dispute-resolution mechanisms meaningful.

As the statutes' repeated emphases on anti-duplication and dispute resolution make clear, *see* 42 U.S.C. § 256b(a)(5); *id.* § 256b(d)(3)(A); *id.* § 1320f-2(d); *id.* § 1395w-114b(b)(1)(B), the proper functioning of those processes is a statutorily mandated "salient factor" that HRSA had to consider. *Humane Soc'y of the U.S. v. Zinke*, 865 F.3d 585, 607 (D.C. Cir. 2017). Yet HRSA

made no mention of these goals in its letters purporting to stop manufacturers from implementing programs that would have furthered those statutory objectives. *See, e.g.*, AR 342–344 (BMS Ltr.); AR 292–294 (Lilly Ltr.); AR 202–204 (Johnson & Johnson Ltr.); AR 380–382 (Sanofi Ltr.); AR 439–441 (Novartis Ltr.). Because HRSA has refused to grapple with these important factors, it has fallen far short of "prov[ing]" that it has "considered the relevant priorities." *Stewart*, 313 F. Supp. 3d at 259 (quotation omitted). Likewise, HRSA has failed to "respond meaningfully" to BMS's legitimate objections on these grounds. *See PPL Wallingford Energy LLC v. FERC*, 419 F.3d 1194, 1198 (D.C. Cir. 2005) (quotation omitted); *see also* AR 325–330 (BMS's raising to HRSA the MFP-340B nonduplication, MDRP-340B duplicate discounting, and ADR rationales for the cash-rebate model). For both reasons, HRSA's decision is arbitrary and capricious.

D. HRSA's Disapproval of BMS's Cash-Rebate Model Denies BMS the Only Feasible Means of Preventing MFP-340B Duplication.

HRSA's rejection of BMS's cash-rebate model is also arbitrary and capricious for two reasons specific to the IRA. *First*, HRSA's refusal to runs counter to the IRA's MFP-340B nonduplication entitlement. That component of the IRA provides that manufacturers must offer only the lower of the MFP or the 340B ceiling price if a prescription is subject to both reduced prices, not both. 42 U.S.C. § 1320f-2(d). Yet HRSA's disapproval letter, when read together with CMS's guidance, effectively eliminates the nonduplication protection the statute guarantees. For its part, HHS has not provided for any meaningful mechanism to identify 340B units and thereby enable manufacturers to effectuate the statutory guarantee of MFP-340B nonduplication. CMS has instead told manufacturers to figure it out themselves. *See* CMS 2027 IRA Guidance at 232. Any mechanism to do so requires data on the 340B status of each prescription, which only the covered entities possess. The only mechanism BMS and other manufacturers have to access those data and deduplicate 340B and MFP price concessions is the cash-rebate model. But HHS, through

HRSA, has refused to approve the model, rendering the IRA's MFP-340B nonduplication provision "a mere nullity." *Orion Rsrvs. Ltd. P'ship*, 553 F.3d at 703 (quoting *Manhattan Gen. Equip. Co. v. Comm'r*, 297 U.S. 129, 134 (1936)). Because regulatory action "contrary to a statute is void," *id.*, HRSA's disapproval letter and policy regarding cash-rebate models generally is contrary to law and should be set aside.

Second, HHS's refusal defies logic. BMS's letter to HRSA specifically called out the problem of MFP-340B duplication and the need to implement its cash-rebate model in time to inform its MFP effectuation plan. AR 327–330, AR 334. Yet HRSA's letter does not explain why it is withholding approval of the model despite these concerns. That is quintessential arbitrary action; an agency must "respond meaningfully to the arguments raised before it." *New England Power Generators Ass'n v. FERC*, 881 F.3d 202, 210 (D.C. Cir. 2018) (citation omitted). HRSA has "failed to respond to the substantial arguments put forward by" BMS about MFP-340B duplication, *id.* at 211, and "provided no reasoned explanation for how its decision comports with . . . the purposes of" the IRA, *West Deptford Energy, LLC v. FERC*, 766 F.3d 10, 12 (D.C. Cir. 2014). HRSA's "*ipse dixit* conclusion, coupled with its failure to respond to contrary arguments resting on solid data, epitomizes arbitrary and capricious decisionmaking." *Illinois Pub. Telecomms. Ass'n v. FCC*, 117 F.3d 555, 564 (D.C. Cir. 1997) (per curiam).

HRSA's rejection of BMS's cash-rebate solution is especially irrational because HHS has disclaimed any responsibility to ensure that the IRA's nonduplication protection is effectuated. *See* CMS 2027 IRA Guidance at 231 ("CMS will not, at this time, assume responsibility for nonduplication of discounts between the 340B ceiling price and MFP."); *see also id.* at 54 ("Neither CMS nor [its contractor] will verify that a claim was or was not billed as a 340B-eligible drug."). HHS cannot instruct drug manufacturers to comply with a statutory directive, refuse to

provide any support, and then forbid the only viable solution that also guarantees the protection afforded by that same statutory mandate. That result is "neither 'logical' nor 'rational,' " *Fox*, 684 F.3d at 80 (quoting *Tripoli Rocketry Ass'n v. ATF*, 437 F.3d 75, 77 (D.C. Cir. 2006)), and HRSA's letter lacks any rationale to support that an outcome. *See Siegel v. SEC*, 592 F.3d 147, 164 (D.C. Cir. 2010) (vacating the SEC's order as "an abuse of discretion" where "[t]he SEC . . . cited no controlling precedent that include[d] reasoned decisionmaking supporting" its decision).

E. HRSA's Position Defies Common Sense.

Finally, HRSA's position simply runs counter to common sense. The agency has attempted to shut down a system with undeniable policy benefits—a system that would fix several of the 340B program's most serious shortcomings, benefiting all stakeholders. The APA does not permit an agency to spurn good governance, particularly without an explanation.

Agencies may not act "in defiance of common sense to reach an illogical result." *Evergreen Shipping Agency (Am.) Corp. v. Fed. Mar. Comm'n*, 106 F.4th 1113, 1117–18 (D.C. Cir. 2024). Agencies' decisionmaking processes must therefore be rational and discernable, *Tripoli Rocketry Ass'n*, 437 F.3d at 77, and an agency cannot "ignore an obvious fact," *Grayscale Invs.*, 82 F.4th at 1248 (quotation omitted and alteration adopted). Nor should an agency act for "reasons not mentioned in the regulations." *Menkes v. DHS*, 486 F.3d 1307, 1313 (D.C. Cir. 2007).

HRSA violated those principles here by closing its eyes to the various programmatic benefits the cash-rebate model offers over the product-replenishment model. Most importantly, the cash-rebate model will reinvigorate the 340B statute's guardrails. On top of the ways already discussed, *supra* pp. 18–20, the cash-rebate model eliminates the current practice of commingling 340B and non-340B inventory. The current accounting fiction in which units purchased at a 340B price are treated as neutral inventory that can be dispensed to any subsequent patient flagrantly violates the 340B statute's direction not to "resell or otherwise transfer [a] drug" purchased at the

340B price "to a person who is not a [340B] patient." *See* 42 U.S.C. § 256b(a)(5)(B). The cash-rebate model would end that shell game because a unit would clearly and permanently be identified as either subject to 340B compliance obligations, or not.

The cash-rebate model will also create practical benefits that address the worst shortcomings of the product-replenishment model. The cash-rebate model will help all stakeholders by using state-of-the-art technology to generate and share data that will enable informed decision-making. AR 338. It will streamline the cash flow by cutting out third-party administrators and contract pharmacies from the payment chain, in favor of direct deposits. And BMS expects to be able to pay rebates to covered entities promptly after receiving a claim. AR 330. That means covered entities will often receive rebates *before* they must pay wholesalers for a unit purchase, likely improving covered entities' cash flow compared to the current full-package requirement. *See id*. In short, the cash-rebate model is more compliant, more efficient, more transparent, and faster than the product-replenishment model.

HRSA did not identify any harms that could offset those benefits. Once again, it simply did not evaluate those benefits at all. *See Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 241 (D.C. Cir. 2008) (faulting the agency for "offer[ing] no reasoned explanation for its dismissal of empirical data that was submitted at its invitation"); AR 342–345. Instead, HRSA has offered a non sequitur: It complained to Johnson & Johnson that the cash-rebate model is supposedly unlawful because it is "not voluntary for covered entities," in contrast to the product-replenishment model, which covered entities created on their own authority. AR 202. But neither the statute nor HRSA's regulations says anything about covered entities getting to choose exactly how they receive the 340B ceiling price. *See* 42 U.S.C. § 256b(a)(1) (providing for either "rebate[s] or discount[s]"); *see also Novartis*, 102 F.4th at 461 (holding that "statutory silence" cannot be

interpreted "to subject manufacturers to whatever delivery conditions any covered entity might find most convenient"); *Sanofi*, 58 F.4th at 704 ("HHS suggests that covered entities get to fill in th[e] blanks so long as they foot the bill. But when Congress's words run out, covered entities may not pick up the pen."). So HRSA may not privilege that made-up justification over the many statute- and regulation-based justifications for the cash-rebate model—especially without bothering to address them. *See Menkes*, 486 F.3d at 1313; *Grayscale Invs.*, 82 F.4th at 1248.

Nor would the cash-rebate model create offsetting harms that HRSA neglected to mention. Critically, BMS would not use the cash-rebate model to deny any covered entities access to 340B prices. *See* AR 318, AR 338. BMS would instead use the claims data generated by the cash-rebate model to work with state Medicaid programs to resolve duplicate MDRP rebates, *id.*; to participate in CMS's process for correcting erroneous IRA inflation-rebate calculations, *see* 340B Drug Pricing Program, 89 Fed. Reg. at 98,598; to pay IRA-mandated MFPs timely and correctly, *see* 42 U.S.C. § 1320f-2(d); and, as needed, to initiate audits and ADR proceedings as provided by the 340B statute, *see id.* § 256b(d)(3)(A). Put differently, the cash-rebate model would strengthen existing legal processes without posing new risks to covered entities or imposing further costs on them. It is hard to imagine a more illogical result than rejecting those improvements in favor of a status quo that is slow, bloated, opaque, unfair, and honeycombed with fraud, waste, and abuse. HRSA's decision—and its lack of explanation for that decision—thus violate the APA and should be vacated. *See, e.g.*, *Evergreen Shipping Agency*, 106 F.4th at 1118.

IV. HRSA'S DISAPPROVAL OF BMS'S CASH-REBATE MODEL VIOLATES BMS'S CONSTITUTIONAL RIGHT TO SUBSTANTIVE DUE PROCESS.

The Fifth Amendment's Due Process Clause prohibits the government from depriving a regulated entity of a constitutionally protected property interest in a way that is so arbitrary as to shock the conscience, regardless of the process used to do so. U.S. Const. amend. V; *see County*

of Sacramento v. Lewis, 523 U.S. 833, 846–847 (1998). BMS can satisfy that showing by establishing "a deliberate flouting of the law that trammels significant personal or property rights." *Tri Cnty. Indus., Inc. v. District of Columbia*, 104 F.3d 455, 459 (D.C. Cir. 1997) (citation omitted); *see also* 5 U.S.C. § 706(2)(B) (the APA forbids agency action that is "contrary to constitutional right").

BMS has a constitutionally protected property interest in covered outpatient drugs that are subject to the IRA and 340B Program. And the IRA guarantees BMS the right to nonduplication of the MFP and 340B price concessions on its sales of Eliquis. 42 U.S.C. § 1320f-2(d). Yet HRSA's inexplicable rejection of BMS's cash-rebate model—at odds with CMS's guidance urging manufacturers to devise just such a model, *see* CMS 2027 IRA Guidance at 232—deliberately flouts the IRA's nonduplication provision. HRSA's letter provides no explanation for its decision, apart from its (incorrect) assertion that "[t]o date, the Secretary has not provided for such a [cash] rebate model." AR 342. HRSA's position is so irrational, "so outrageous," that it "shock[s] the contemporary conscience." *Lewis*, 523 U.S. at 847 n.8. That's because CMS's guidance and HRSA's disapproval letter, in combination, subject BMS to an unconstitutionally untenable dilemma: It can either fill a covered entity's 340B product-replenishment orders and succumb to costly MFP-340B duplication, or it can deny MFP rebates when claimed by a covered entity purchasing 340B-priced products and face staggering civil monetary penalties. *See* 42 U.S.C. § 256b(d)(1)(B)(vi)(II) (instituting civil monetary penalties of up to $7,034 "for each instance of overcharging a covered entity that may have occurred" under the 340B program); Annual Civil Monetary Penalties Inflation Adjustment, 89 Fed. Reg. 64,815, 64,819 (Aug. 8, 2024) (adjusting the statutory amount for inflation); 42 U.S.C. § 1320f-6(a) (imposing civil monetary penalties "equal to ten times the amount" of the (inadvertent) overcharges on MFP rebates). HHS has

destined manufacturers for failure, and its "heads I win, tails you lose" position is irrational in the extreme.

Moreover, the "choice" facing manufacturers—between forgoing a statutorily guaranteed right to MFP-340B nonduplication and violating federal law—is no choice at all, and illustrates that HHS's actions are "genuinely drastic," amounting to a constitutional violation. *Tri Cnty. Indus.*, 104 F.3d at 459. HRSA's threats against other manufacturers, too, confirm how drastic its actions are. HRSA has publicly and uniformly refused to allow manufacturers to implement their cash-rebate models, warning those that publicly announced that they were moving forward with a cash-rebate model told that if they did so without HRSA's preapproval, HRSA could terminate their PPA—and with it, the availability of federal funds under Medicaid and Medicare Part B for their products—as well as assess civil monetary penalties. AR 403, AR 425.

BMS reasonably fears the same reprisal. If BMS's PPA were terminated, none of its drugs would be eligible for Medicare Part B or Medicaid reimbursement. McCarthy Decl. ¶¶ 4, 28. The harm that would result from BMS being excluded from those federal healthcare programs—both to the company and to the patients who depend on BMS's life-changing medicines—is precisely the kind of "grave unfairness," wrought by government actors, that the Fifth Amendment prohibits. *George Washington Univ. v. District of Columbia*, 318 F.3d 203, 209 (D.C. Cir. 2003) (citation omitted). HHS's refusal, through HRSA, to approve BMS's cash-rebate model and HRSA's policy regarding cash-rebate models generally are therefore unlawful under the Fifth Amendment and should be vacated and set aside.

CONCLUSION

For the foregoing reasons, BMS's motion for summary judgment should be granted.

Respectfully submitted,

/s/ Sean Marotta
Sean Marotta (D.C. Bar No. 1006494)
Marlan Golden (D.C. Bar No. 1673073)
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-4881
sean.marotta@hoganlovells.com

Attorneys for Bristol Myers Squibb Company

Dated: February 3, 2025