IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION, 59 Route 10, East Hanover, New Jersey 07936; *Plaintiff*, v. XAVIER BECERRA, in his official capacity as SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue, S.W., Washington, D.C. 20201; and CAROLE JOHNSON, in her official capacity as ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION, 5600 Fishers Lane, Rockville, Maryland 20852, *Defendants*.	Civil Action No. 25-117

COMPLAINT

Plaintiff Novartis Pharmaceuticals Corporation (Novartis) brings this Complaint against Defendants Xavier Becerra, in his official capacity as Secretary of the Department of Health and Human Services (HHS), and Carole Johnson, in her official capacity as Administrator of the Health Resources and Services Administration (HRSA), and alleges as follows:

PRELIMINARY STATEMENT

1. Under the federal 340B Drug Pricing Program, drug manufacturers must offer to sell their products to certain healthcare providers called "covered entities" at significantly reduced

prices. The statute provides that manufacturers may do so either through a discounted price at the time of sale or through a post-sale rebate. Whatever form the price reduction takes, the resulting savings were intended to serve a noble purpose: to allow covered entities to provide care to vulnerable, under-resourced populations.

2. Despite the program's intended aims, the temptations created by access to the profit spread created by these heavily discounted medicines proved too great over time. Increasingly, some covered entities—often with the help of for-profit third-parties—are abusing their access to maximize their profits, ballooning the 340B Program in the process.

3. The program's current default model for effectuating the 340B price—the "product-replenishment" model—obscures whether covered entities claiming 340B pricing on a given purchase are actually entitled to the 340B price. And covered entities have used that opacity to fuel Program growth.

4. Here's how the product-replenishment model works: Covered entities first buy a full package of a drug at the market price and place it in common inventory. The covered entity either stocks the drug in its own pharmacy for dispensing on-site, or, increasingly, contracts with a third-party pharmacy, like Walgreens or CVS, for dispensing off-site and has the product shipped there for the contract pharmacy to stock in its own inventory. In either case, the medicine is dispensed to any individuals with prescriptions. Later, the covered entity, generally through a for-profit third-party administrator, analyzes the transactions to identify those which it thinks may have been 340B-eligible. When the covered entity has identified enough supposedly eligible prescriptions to make up a full package size, it replaces the initial purchase with a new "product replenishment" order at the discounted 340B price. The covered entity or contract pharmacy, depending on where the replenishment order originates from, then places that new order in common

inventory, and the cycle begins again. The product-replenishment model became the default method because covered entities made it so; the 340B statute says nothing about it.

5. Under this model, covered entities do not provide drug manufacturers with data showing why the purchases for which they claim a 340B price are actually 340B-eligible, and manufacturers have no way to readily find out on their own. Moreover, covered entities commonly claim the 340B price on replenishment orders weeks or even months after the supposedly 340B-eligible prescription was filled and well after rebates may be claimed on those same prescriptions under other federal drug-pricing programs, frustrating statutory provisions that prohibit such duplicate price reductions. The result, unsurprisingly, has been a 340B Program rife with incorrectly accessed discounts and misused 340B product, in eye-popping volumes that have increased without any apparent limit.

6. When Congress created the 340B Program, it tried to prevent exactly this sort of abuse. The statute forbids two important forms of wrongdoing: (1) duplicating discounts by claiming both the 340B price and a Medicaid rebate for the same drug, and (2) diverting medicine purchased at the 340B price to individuals who are not eligible for that price. To enforce those prohibitions, Congress allowed manufacturers to audit covered entities and created an administrative dispute-resolution process.

7. But these statutory protections cannot work when manufacturers do not have information about whether covered entities are complying with them. Under the product-replenishment model, that is exactly the problem: covered-entity compliance is a black box. And that problem is about to get worse. Two recently created federal programs will soon add to the thicket of federal drug-pricing requirements, and those requirements cannot be harmonized without—again—340B-

elibibility information possessed by covered entities but shielded from manufacturers and from HHS by the product-replenishment model.

8. Novartis's solution is one contemplated by Congress and included in the 340B statute. Novartis intends to give covered entities 340B prices using a cash-rebate system instead of the current convoluted and deeply flawed product-replenishment system. Under Novartis's cash-rebate system, covered entities would first buy Novartis's medicines at commercial prices, as they do now. After identifying a prescription as 340B-eligible, a covered entity would submit a 340B-rebate claim to Novartis electronically. Novartis would then pay the covered entity cash representing the difference between the commercial price and the 340B price. That method would be faster, simpler, and more transparent, and it would give Novartis the information it needs to restore the 340B statute's guardrails and meet its legal pricing obligations.

9. Novartis notified HRSA of its plans, asking HRSA to confirm that Novartis was free to implement its cash-rebate model as allowed by both the 340B statute and Novartis's agreement reflecting its participation in the 340B program.

10. HRSA refused to confirm the legality of Novartis's model. HRSA stated that because the "Secretary has not provided for such a rebate model," Novartis "implementing such a model at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval of Novartis's proposed rebate model." Even though HRSA took the position that Novartis's implementation of its cash-rebate model would violate the 340B statute, HRSA also stated that "[t]he Secretary has neither approved nor disapproved Novartis' rebate model."

11. HRSA's response to Novartis is of a piece with HRSA's responses to other manufacturers that have announced their intentions to implement similar cash-rebate models. HRSA

has told other manufacturers that they cannot proceed without agency preapproval and even threatened one manufacturer with civil monetary penalties and termination from the 340B Program, which in turn would also terminate federal Medicaid and Medicare Part B funding for that manufacturer's drugs. HRSA has posted its threats to other manufacturers on its website and stated, unequivocally, that "implementing a rebate proposal without Secretarial approval would violate Section 340B(a)(1) of the Public Health Service Act." And HRSA has previously stated that it would "not consider" the use of a cash-rebate model for the covered entities to which Novartis intends to apply its cash-rebate model. Notice Regarding Section 602 of the Veterans Health Care Act of 1992—Rebate Option, 63 Fed. Reg. 35,239, 35,241-42 (June 29, 1998).

12. HRSA's view that manufacturers cannot use a cash-rebate model without the agency's preapproval is a novel one. A cash-rebate system has existed as to certain covered entities for decades without HRSA preapproval, and HRSA has never approved—before or after its adoption—the product-rebate model that most covered entities use today. And the current product-replenishment model is a rebate model, too—covered entities initially buy a package of medicine at commercial prices and later claim a rebate from manufacturers in the form of 340B-priced replacement medicine. Even so, HRSA has threatened drug manufacturers with drastic consequences if they launch their cash rebate models without HRSA's preapproval, which it has refused to provide.

13. HRSA's position is unlawful for at least four reasons. *First*, neither the 340B statute nor Novartis's agreement with HRSA implementing the statute requires Novartis to provide the 340B price in any particular way. In fact, the statute expressly allows rebates—as both its text and its legislative history confirm—and Novartis's agreement with HRSA is silent as to the manner for effectuating the 340B price. Novartis is therefore allowed to offer the required pricing through

a rebate and may do so without HRSA's advance permission. HRSA violated the 340B statute and exceeded its authority by purporting to bar an option the statute expressly permits, using a claimed power the statute does not give it.

14. *Second*, HRSA's position is arbitrary and capricious. Without a cash-rebate model, Novartis will continue to be forced to provide 340B pricing when it has no statutory obligation to do so. HRSA's refusal also rests on treating indistinguishable scenarios—as well as different stakeholders in the process—differently without explanation and ignoring that the agency has never before asserted the preapproval power it now claims to possess even when other entities have implemented a rebate model. And in multiple ways, HRSA's decision frustrates the 340B statute's important guardrails.

15. *Third*, HHS is violating Novartis's substantive-due-process rights by subjecting it to inconsistent demands. HRSA—a subagency of HHS—is refusing to allow Novartis to implement its cash-rebate model while also charging Novartis—through another subagency of HHS—to comply with a different statute using information that only a cash-rebate model can provide. HHS has thus left Novartis with no way to satisfy all of its directives. As a result, Novartis must choose between offering significant price concessions that it has no legal obligation to provide or facing crushing civil monetary penalties. That outcome is so irrational that it shocks the conscience in violation of the Fifth Amendment.

16. *Fourth*, HRSA's position violates Novartis's procedural-due-process rights in two respects. Under the product-replenishment model, Novartis is erroneously deprived of protected property interests in its medicines by being forced to provide 340B prices in many instances where it has no legal obligation to do so. Novartis has only one way to be heard regarding claims that it has been erroneously deprived of these protected property interests—the statutory administrative

process for resolving disputes. But HRSA's decision ensures that Novartis will almost never have enough information to access that process, leaving Novartis with no meaningful opportunity to be heard. HRSA's refusal to approve Novartis's cash-rebate model and its policy generally regarding cash-rebate models also makes it difficult, if not impossible, to obtain documentation necessary to support denials of improperly claimed duplicate pricing between the Inflation Reduction Act of 2022's "Maximum Fair Price" and the 340B price. HRSA's actions will therefore deprive Novartis of access to HHS's "Maximum Fair Price" rebate-dispute procedures unless Novartis is willing to potentially expose itself to significant civil monetary penalties, again with no meaningful opportunity to be heard.

PARTIES

17. Plaintiff Novartis Pharmaceuticals Corporation is a corporation organized in Delaware with its principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

18. Defendant Xavier Becerra is the Secretary of HHS. Defendant Becerra maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201. He is sued in his official capacity only.

19. Defendant Carole Johnson is the Administrator of HRSA, an operating component within HHS. Defendant Johnson maintains an office at 56000 Fishers Lane, Rockville, Maryland 20852. She is sued in her official capacity only.

JURISDICTION AND VENUE

20. This Court has jurisdiction under the following statutes:

a. 28 U.S.C. § 1331, because this civil action arises under the laws of the United States;

b. 28 U.S.C. § 1346(a)(2), because Novartis asserts claims against the United States;

c. 28 U.S.C. § 1361, because this is an action to compel officers of the United States to perform their duties; and

d. 28 U.S.C. §§ 2201–02, because this is an actual, justiciable controversy as to which Novartis requires a declaration of its rights by this Court and injunctive relief to prohibit Defendants from violating laws and regulations.

21. Venue is proper in this Court under 28 U.S.C. § 1391(e)(1)(A) because this is a civil action in which Defendants are officers of the United States acting in their official capacities, and at least one defendant resides in this judicial district.

FACTUAL BACKGROUND

The 340B Program

22. Congress created the 340B Drug Pricing Program in 1992. Under the 340B Program, participating pharmaceutical manufacturers must offer covered outpatient drugs to qualifying hospitals and clinics that primarily serve certain vulnerable patient populations—called "covered entities"—at a deeply reduced price, known as the "ceiling price." 42 U.S.C. §§ 256b(a), (a)(4), (b)(1).

23. Courts have recognized that a manufacturer satisfies the statute's "shall offer" requirement so long as it makes a "bona fide" offer to sell its medicines to covered entities at or below the ceiling price. A manufacturer may therefore attach reasonable conditions to its offer, including data-reporting conditions. *See, e.g.*, *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 461 (D.C. Cir. 2024) (embracing HHS's decades-long policy allowing manufacturers' "reasonable conditions"); *see also Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 701, 706 (3d Cir. 2023) (permitting a manufacturer requirement that covered entities provide claims data).

24. The 340B Program works by making manufacturers' federal reimbursements for their products under Medicaid and Medicare Part B conditioned on the HHS Secretary "enter[ing]

into an agreement with [the] manufacturer." 42 U.S.C. § 256b(a)(1); *see also id.* § 1396r-8(a)(1). The agreement, known as a Pharmaceutical Pricing Agreement or PPA, "incorporate[s] the 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).

Statutory Background

25. The 340B statute gives participating manufacturers two ways to provide the 340B price: a "rebate" or a "discount." 42 U.S.C. § 256b(a)(1). The statute requires manufacturers to "enter into an agreement"—the PPA—"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 . . . does not exceed" the ceiling price. *Id.*

26. The 340B statute repeatedly reflects that manufacturers may choose between rebates and discounts. For example, the statute's anti-duplication provision "prohibit[s] duplicate discounts *or* rebates." 42 U.S.C. § 256b(a)(5) (emphasis added). When the statute defines the ceiling price, it provides for a reduction of the "average manufacturer price" by the "*rebate* percentage." *See id.* § 256b(a)(2) (emphasis added). And the statute also creates a "mechanism" for reporting "rebates and other discounts" and ensuring that "such discounts or rebates" result in the appropriate ceiling price. *See id.* § 256b(d)(1)(B)(iv).

27. The legislative history, too, reflects this rebate-or-discount choice. The House Committee on Energy and Commerce noted that the statute "does not specify" whether 340B prices should be offered "through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism." H.R. Rep. No. 102-384(II), *16 (1992).

28. Even HRSA has acknowledged that the statute expresses no preference between rebates and discounts. In endorsing a longstanding method of providing 340B prices to certain covered entities through cash rebates, HRSA explained that "Section 340B has no explicit

language as to whether the required reduction in price should be obtained by . . . a discount mechanism [or] a rebate option." 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) (citing H.R. Rep. No. 102-384(II), *16 (1992)).

29. HRSA has not purported to mandate by regulation the use of either discounts or rebates. Nor could it; the agency's limited rulemaking authority does not extend to dictating the form in which the 340B price must be effectuated. *See Pharm. Rsch. & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014) (noting HRSA's limited rulemaking authority). Manufacturers' PPAs likewise do not direct the 340B price to be effectuated in any particular way.[1]

30. Congress knew the 340B Program's significant financial benefits could lead to abuse. So Congress provided protections to help "assure the integrity of the drug price limitation program." H.R. Rep. No. 102-384(II), *9–10 (1992). Two are especially relevant here. First, covered entities cannot receive 340B pricing for medicine that is also eligible for a rebate under the Medicaid Drug Rebate Program (MDRP). *See* 42 U.S.C.§ 256b(a)(5)(A). Second, covered entities cannot divert product that has been purchased at the 340B price to individuals who are not patients of the covered entity. *See id.* § 256b(a)(5)(B).

31. The 340B statute also limits the availability of 340B pricing. Only a covered entity need receive the reduced price, *see* 42 U.S.C. § 256b(a)(1), and the statute limits that defined term to entities that, among other things, comply with the anti-duplication and anti-diversion prohibitions, *see id.* § 256b(a)(4). A manufacturer therefore need not offer 340B pricing for a unit that is

[1] HRSA uses a form PPA and PPA Addendum for every manufacturer. *See* Pharmaceutical Pricing Agreement, HHS, HRSA, Healthcare Sys. Bureau, OMB No. 0915-0327, https://www.hrsa.gov/sites/default/files/hrsa/opa/manufacturer-ppa.pdf; Pharmaceutical Pricing Agreement Addendum, HHS, HRSA, Healthcare Sys. Bureau, OMB No. 0915-0327, https://www.hrsa.gov/sites/default/files/hrsa/opa/manufacturer-ppa-addendum.pdf. Novartis's PPA conforms to these forms.

subject to an MDRP rebate or is provided to someone who is not a patient of a covered entity. Manufacturers also need not offer the 340B price to more than one covered entity for a given unit. *See id.* § 256b(a)(1).

32. Congress created procedures to help police the 340B Program's limitations. First, it directed HHS's Secretary to create an Administrative Dispute Resolution (ADR) mechanism to resolve disputes between manufacturers and covered entities. 42 U.S.C. § 256b(d)(3)(A); *see also* 340B Drug Pricing Program, 89 Fed. Reg. 28,643 (Apr. 19, 2024); 42 C.F.R. § 10.21(a). Congress also allowed manufacturers to audit covered entities' records that that "directly pertain to the entity's compliance" with the duplication and diversion prohibitions. 42 U.S.C. § 256b(a)(5)(C). The two procedures are interrelated; a manufacturer cannot initiate an ADR proceeding unless it has first completed an audit. *Id.*

33. HRSA has weakened these procedures and the protection they provide. HRSA requires manufacturers to show "reasonable cause" to initiate an audit by first adducing "sufficient facts and evidence in support" of a claim that a covered entity has misused the 340B Program. Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406, 65,410 (Dec. 12, 1996) (Audit Guidance). A manufacturer therefore cannot begin an audit—or, by extension, ADR proceedings—unless it first has information about a covered entity's practices.

The 340B Program Is Plagued by Rampant Covered-Entity Noncompliance

34. The 340B Program is plagued by covered-entity noncompliance, as multiple federal agencies—including HRSA—have documented.

35. To start, HHS audits consistently find widespread violations of the MDRP-340B-duplication and 340B-diversion prohibitions. *See, e.g.*, HRSA, Audit Results of Covered Entities https://www.hrsa.gov/opa/program-integrity; Government Accountability Off. (GAO), *HHS Uses*

Multiple Mechanisms to Help Ensure Compliance with 340B Requirements, GAO-21-107 at 14 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf (2020 GAO Report) (noting 1,536 instances of noncompliance uncovered by HHS audits from 2012 to 2019 alone).

36. GAO has both confirmed those findings and attributed them in part to HHS's lackluster oversight. A January 2020 GAO report found that HHS cannot provide "reasonable assurance that states and covered entities are complying with the prohibition on [MDRP-340B] duplicate discounts." GAO, *340B Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement*, GAO-20-212 (Jan. 2020), https://www.gao.gov/assets/gao-20-212.pdf (GAO Highlights). GAO concluded that "[l]imitations in federal oversight impede [HHS's] ability to ensure compliance with the prohibition on [MDRP-340B] duplicate discounts" and that HHS's failure to ensure compliance with 340B Program requirements "not only puts drug manufacturers at risk of providing [MDRP-340B] duplicate discounts, but also compromises the integrity of the 340B Program." *Id*. at 27.

37. GAO also pointed out that these problems have worsened over time because of both "substantial growth in the 340B Program" and the MDRP's "expansion." GAO Highlights at 2. GAO highlighted HHS's prior findings acknowledging "challenges covered entities and states face in identifying 340B drugs provided to Medicaid beneficiaries, and thus in preventing duplicate discounts." *Id.* at 3 (citing HHS Off. of Inspector Gen. (OIG), *State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates*, OEI-05-14-00430 (June 2016), https://oig.hhs.gov/documents/evaluation/2918/OEI-05-14-00430-Complete%20Report.pdf; National Ass'n of Medicaid Dirs., *Medicaid and the 340B Program: Alignment and Modernization Opportunities* (May 2015), https://medicaiddirectors.org/wp-content/uploads/2022/02/NAMD-White-Paper-on-Medicaid-and-340B-Alignment_pdf.pdf; and Medicaid & CHIP Payment & Access Comm'n, *The 340B*

Drug Pricing Program and Medicaid Drug Rebate Program: How They Interact (May 2018), https://www.macpac.gov/wp-content/uploads/2018/05/340B-Drug-Pricing-Program-and-Medicaid-Drug-Rebate-Program-How-They-Interact.pdf).

38. Even before these findings, GAO had identified "weaknesses in HRSA's oversight that impede its ability to ensure compliance with 340B Program requirements, including the prohibition on duplicate discounts." GAO, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480 (June 2018) (2018 GAO Report), https://www.gao.gov/assets/d18480.pdf. For example, "HRSA audits do not assess for the potential for duplicate discounts in Medicaid managed care," and HRSA "does not require covered entities to take the same actions to address duplicate discounts for managed care claims that HRSA learns about through its audits or other means." *Id*. at 25–26.

39. The managed-care gap is "particularly problematic" because Medicaid managed care accounts for "the majority" of Medicaid prescriptions and drug spending and likely the majority of "duplicate discounts." 2018 GAO Report at 26. And managed care accounts for more than 70 percent of Medicaid enrollment, so neglecting this area effectively renders the statute's anti-duplication protection meaningless. *See* Kaiser Family Foundation, *10 Things to Know About Medicaid Managed Care* (May 1, 2024), https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-managed-care/. HRSA's audits therefore cannot "provide the agency with reasonable assurance that covered entities are taking the necessary steps to prevent duplicate discounts." 2018 GAO Report at 24–25.

40. These reports are just the tip of the governmental-findings iceberg. Time and again, reports have found that covered-entity opacity has contributed to unlawful duplicate discounts. In just one, 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." House Energy & Commerce Comm., *Review of the 340B Drug Pricing Program* 36–37 (Jan. 10, 2018), https://tinyurl.com/58rpjkf. GAO has similarly explained—in discussing covered entities' self-reported program violations—that "HRSA does not know if covered entities have effectively identified the full extent of noncompliance." GAO, *340B Drug Discount Program: Information About Hospitals That Received an Eligibility Exception as a Result of COVID-19*, GAO-23-106095 (May 11, 2023), https://www.gao.gov/assets/gao-23-106095.pdf.

41. Against this backdrop, the 340B Program has both exploded in size and strayed from its original mission. The 340B Program was supposed to support the care of uninsured, low-income patients. IQVIA, *Unintended Consequences: How the Affordable Care Act Helped Grow the 340B Program* (Aug. 30, 2024), https://www.iqvia.com/locations/united-states/library/white-papers/unintended-consequences-how-the-affordable-care-act-helped-grow-the-340b-program. Thanks in part to the Affordable Care Act's Medicaid's expansion, the number of uninsured patients has "almost halved" between 2013 and 2021. *Id.* at 2. Yet during the same time period, 340B revenue has "more than tripled." *Id.* at 8.

42. MDRP-340B duplication has become staggering. One analyst has estimated that as much as five percent of all Medicaid rebates now duplicate 340B pricing, adding up to $2.1 billion in 2020. Ashwin Mundra, *The 340B Noncompliance Data Gap Leaves Drug Manufacturers in the Dark, Drug Channels* (Mar. 18, 2022), https://www.drugchannels.net/2022/03/the-340b-noncompliance-data-gap-leaves.html. That figure is likely even higher today because 340B purchases rose from about $38 billion to about $66 billion between 2020 and 2023. 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), https://www.drugchannels.net/2024/10/the-340b-program-reached-66-billion-in.html. And HRSA's abdication of its responsibility to prevent MDRP-340B duplication has contributed substantially to the problem.

HRSA Has Long Permitted 340B Rebate Models Without Preapproval

43. Manufacturers have long provided 340B prices to covered entities through some form of a rebate model. And HRSA has for many years formally and informally permitted manufacturers to use those rebate models, without pre-approval, such that rebate models are now the dominant method of implementing 340B prices.

Cash Rebates to AIDS Drug Assistance Programs

44. Over 25 years ago, HRSA formally permitted a 340B cash-rebate model for covered entities known as AIDS Drug Assistance Programs, or ADAPs, and it did so without first requiring agency pre-approval. 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), https://ryanwhite.hrsa.gov/about/parts-and-initiatives/part-b-adap.

45. Under the ADAP rebate model, ADAPs pay for drugs at market prices and the manufacturer later gives the ADAP cash that "equal[s] or exceed[s] the discount provided by the statutory ceiling price." Rebate Notice, 62 Fed. Reg. at 45,824. In 1997, after this payment model had already been in effect, HRSA initiated a notice-and-comment process to formally "recognize" this preexisting arrangement as a valid "method of accessing the 340B program. *Id.* Following public comment, HRSA "recognize[d] an ADAP rebate option" as "consistent with the section 340B rebate program" without imposing "in-depth implementation strategies." 63 Fed. Reg. at 35,240. HRSA did not assert preapproval authority over manufacturers' ADAP rebate models either in seeking comment on or in later recognizing the model. HRSA simply allowed ADAPs to

"*continue* to provide utilization data" to access cash rebates "according to terms of *existing* agreements if so desired." *Id.* (emphases added).

46. In recognizing the ADAP rebate model's lawfulness, HRSA also acknowledged the lawfulness of the compliance conditions inherent in a cash-rebate model. For instance, HRSA recommended to ADAPs that they pursue cash rebates using "standard business practices," including by providing "detailed and accurate . . . initial claim data." 63 Fed. Reg. at 35,239–41. HRSA has thus acknowledged that manufacturers providing a cash rebate following the provision of claims data demonstrating eligibility is a standard business practice and further admitted that such standard business practices actually lead to positive outcomes for ADAPs. HRSA currently directs ADAPs to "engage in a thorough cash flow analysis," which can "ensure a continuous cash flow" and "prevent the potential for cash shortages and program service delivery disruption." HIV/AIDS Bureau, AIDS Drug Assistance Program (ADAP) Manual 42 (June 2023), https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/resources/adap-manual.pdf (ADAP Manual).

Product Rebates to All Covered Entities

47. HRSA has also long permitted a product-rebate model, one with a much wider-ranging impact. *See, e.g.*, HRSA, 3*40B Peer-to-Peer Program: 340B Compliance Improvement Guide* 36–37 (Oct. 1, 2015), https://www.hrsa.gov/sites/default/files/hrsa/opa/compliance-improvement-guide.pdf. Often called the "product-replenishment model," this method of providing 340B prices to covered entities is now the default approach for covered entities more broadly. But HRSA has never purported to approve it—before its implementation or otherwise—and manufacturers did not create it. The model instead arises primarily from a covered-entity accounting trick.

48. To understand the product-replenishment model, it is helpful to first consider what it replaced. At the 340B Program's inception, covered entities primarily used a simple physical-inventory model. Under that system, covered entities physically segregated units purchased at 340B prices from units purchased at commercial prices. Covered entities then determined whether a prescription was 340B-eligible before a unit was dispensed. *See* 340B Health, *Key Terms*, https://www.340bhealth.org/members/340b-program/key-terms/; HHS OIG, *Contract Pharmacy Arrangements in the 340B Program,* OEI-05-13-00431 at 5 (Feb. 4, 2014), https://oig.hhs.gov/documents/evaluation/2914/OEI-05-13-00431-Complete Report.pdf (Contract Pharmacy Arrangements). If a prescription was 340B-eligible, the covered entity dispensed a 340B-priced unit. Otherwise, the covered entity dispensed a commercially priced unit.

49. Over time, covered entities—with respect to both their on-site inventories as well as their contract-pharmacy arrangements, which have also ballooned over the years—abandoned the physical segregation of differently priced units and began commingling 340B-priced units and commercially priced units, instead purporting to track them using a virtual-inventory model. Under this approach, a prescription is not identified as supposedly 340B-eligible until after the product has been dispensed, oftentimes weeks or months later. These two corner-cutting measures—commingling inventories and after-the-fact 340B determinations—are the defining features of the product-replenishment model, and they are responsible for much of the 340B Program's unchecked growth and rampant abuse.

50. Here's the accounting trick: A covered entity—or, more likely, its contract pharmacy—first buys a pre-set amount of a drug, called a full package, at market price and places the package in its or the contract pharmacy's common inventory. Over time, the package is dispensed to individuals in smaller amounts, without regard to whether the individuals' prescriptions are

340B-eligible. Later, the covered entity analyzes transactions to assess which ones it thinks it could claim as 340B-eligible—often with the help of for-profit middlemen that are paid based on how many purportedly eligible transactions they identify. When the covered entity has identified enough supposedly eligible prescriptions to add up to a full package, the entity claims that it is entitled to be made whole for already-dispensed product and demands an in-kind rebate of product: a new full package, purchased this time at the 340B price. The covered entity then places the 340B-price full package in its or its contract pharmacy's common inventory, and the cycle repeats.

51. One key problem of the product-replenishment model is that it causes routine violations of the 340B statute's prohibition on diversion. The model inevitably results in covered entities purchasing medicine at a 340B price and then "resell[ing] or otherwise transfer[ring] the drug" to non-340B-eligible individuals. *Contra* 42 U.S.C. § 256b(a)(5)(B). Put differently, a unit of medicine may be treated as a commercial unit for dispensing purposes, but as a 340B unit for pricing purposes. 340B status moves from one unit to another according to what serves the covered entity's interests at a given time, making it impossible for the manufacturer to determine which unit is supposed to be compliant with a covered entity's 340B obligations.

52. HRSA has closed its eyes to this illegality. It acknowledges the ubiquity of the product-replenishment model, characterizing it as anodyne "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), https://perma.cc/L7W2-H597. Even so, HRSA has never purported to approve the product-replenishment model and has never claimed that the product-replenishment model requires preapproval.

53. The product-replenishment model's opacity exacerbates all of these problems. Covered entities not only may take weeks or months to identify transactions as ostensibly 340B-

eligible, but they typically do not share with manufacturers *which* transactions the covered entity believes are 340B eligible or *why* the covered entity believes those transactions are eligible.

54. That problem is particularly acute when covered entities employ third parties to make eligibility determinations. These contractors compete with one another based on their ability to identify as many supposedly 340B-eligible transactions as possible—maximizing revenue for covered entities—and many contractors employ proprietary algorithms to identify such transactions. *See* Aaron Vandervelde et al., Berkely Rsch. Grp., *For-Profit Pharmacy Participation in the 340B Program* 5 (Oct. 2020), https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRGForProfitPharmacyParticipation340B_ 2020.pdf; Neal Masia, Ph.D., Alliance for Integrity & Reform, *340B Drug Pricing Program: Analysis Reveals $40 Billion in Profits in 2019* at 2, https://340breform.org/wpcontent/uploads/2021/05/AIR340B-Neal-Masia-Report.pdf; *see also Novartis*, 102 F.4th at 457–458. The upshot: Manufacturers don't get the information they need to verify 340B eligibility, a result completely at odds with standard and reasonable commercial business practices, where discounting simply is not provided absent evidence of eligibility, as HRSA itself has acknowledged in the ADAP context.

55. The product-replenishment model's secrecy also frustrates the statutory audit and ADR processes. Because covered entities do not share the information underlying their 340B-eligibility determinations, manufacturers cannot know whether a prescription has been subject to MDRP-340B duplication. But under HRSA's current guidance, the manufacturer's lack of data means it often does not have "sufficient facts and evidence in support" of "reasonable cause" to support an audit request. Audit Guidance, 61 Fed. Reg. at 65,410. And if the manufacturer cannot audit a covered entity, it cannot bring an ADR claim against the covered entity. 42 U.S.C.

§ 256b(d)(3)(A); 42 C.F.R. § 10.21(a)(2). The product-replenishment model as it is practiced today thus effectively nullifies the 340B statute's duplication and diversion prohibitions.

56. Whatever its many failings, the product-replenishment model is a rebate model. Covered entities that employ the product-replenishment model do not receive 340B prices until after they have first made a purchase at a higher, market price—a rebate model's defining feature. *See, e.g.*, Oxford English Dictionary (defining "rebate" as a "deduction from a sum of money to be paid," especially "one given retrospectively"); Cambridge Dictionary (defining "rebate" as "money that is returned to you after you pay for goods or services"); Merriam-Webster Dictionary (defining "rebate" as "a return of part of a payment"); Britannica Dictionary (defining "rebate" as "an amount of money that is paid back to you").

The IRA's Drug Price Negotiation Program and Inflation Rebates

57. The harms inflicted by the product-replenishment model are about to get even more severe due to two aspects of the Inflation Reduction Act (IRA). The first arises from the IRA's "Drug Price Negotiation Program," which requires the Centers for Medicare & Medicaid Services (CMS) to impose a price control the IRA calls a "maximum fair price" (MFP). Manufacturers must honor MFPs for Medicare units of certain drugs, including Novartis's Entresto. The second arises from the IRA's creation of 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. To correctly implement IRA MFPs, drug manufacturers need 340B-eligibility information that the product-replenishment model denies them. And CMS, too, cannot correctly calculate inflation rebates without timely information about units for which manufacturers have provided 340B prices.

58. The Drug Price Negotiation Program directs HHS's Secretary to "enter into agreements with manufacturers of selected [Medicare Part B and Part D] drugs," under which the

Secretary will impose an MFP for the selected drug. 42 U.S.C. § 1320f-2(a). The manufacturer must then "provide access to such price" with respect to Medicare beneficiaries. *Id.* § 1320f-2(a)(1). That discounting obligation can overlap with the 340B ceiling price, as Congress recognized. The IRA therefore 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. *Id.* § 1320f-2(d). This "nonduplication" provision accordingly pairs an obligation—the manufacturer must offer the lower of the MFP or 340B prices—with a protection—nonduplication of the two prices' respective reductions. Manufacturers are subject to the lower-price obligation conditioned on their receipt of the non-duplication protections.

59. CMS, for its part, has embraced a rebate model for effectuating MFPs, giving manufacturers the discretion to choose between a rebate model and a discount model. 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* 198 (Oct. 2, 2024), https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf (CMS 2027 IRA Guidance). CMS also directs manufacturers to "ensure that the appropriate price concession is honored, consistent with their obligations under [the IRA], and inclusive of their agreements under" the 340B Program. *Id.* at 230.

60. Under the current product-replenishment model, complying with the directive is functionally impossible. The 340B cash-rebate model is necessary where 340B eligibility is a possibility because there is no other way for manufacturers to provide the "lower of" the MFP or 340B price as the IRA mandates. The "lower of" determination requires that a manufacturer ascertain whether a given unit is eligible for the MFP, the 340B price, or both. And that knowledge

can be gained only once the unit has been dispensed, the recipient is identified as a Medicare patient, and the prescription is identified as 340B-eligible. CMS gives manufacturers a mere 14 days to figure all that out and provide the right "lower" price if manufacturers provide the MFP through a rebate. *See* CMS 2027 IRA Guidance at 196.

61. But CMS has refused to ensure that manufacturers timely receive claims data that indicate whether a particular unit is both 340B and MFP eligible. *See id.* at 202–04 (describing the data manufacturers will receive and noting that "[a] dispensing entity may *voluntarily* apply [certain] indicators to a Part D claim to indicate the claim is being billed for a 340B drug") (emphasis added). And 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. *See* 42 U.S.C. § 1320f-6(a). As a result, under the current product-replenishment system—where 340B product rebate claims are often not submitted to the manufacturers for weeks if not months—Novartis will have to pay a MFP rebate and then, when the 340B product replenishment order comes in, pay that product rebate as well. The coerced-by-penalties double-rebate result created by the current product-replenishment system deprives Novartis of one of the key, if not only, protections it has in the IRA

62. HHS refuses to fill the gap. The agency has disclaimed any responsibility for preventing MFP-340B duplication, announcing that it will not "verify that a claim was or was not billed as a 340B-eligible drug." CMS 2027 IRA Guidance at 54–56. CMS has instead told drug manufacturers to come up with a solution on their own, telling manufacturers that CMS "strongly encourages manufacturers to work with dispensing entities, covered entities and their 340B [administrators], and other prescription drug supply chain stakeholders (e.g., wholesalers) to facilitate access to the lower of the MFP and the 340B ceiling price, wherever applicable." *Id.* at 232.

63. But when manufacturers did just that, HRSA—a subagency of HHS—balked. The only way manufacturers can comply with the IRA-340B nonduplication provisions within the statutorily required 14 days is for manufacturers to receive the data supporting a covered entity's claim of 340B eligibility. HRSA's refusal to let manufacturers require submission of data that covered entities keep in the ordinary course of their businesses constitutes an effective mandate to use the product-replenishment model and prevents manufacturers from answering CMS's charge to get the necessary 340B-eligibility data themselves. Combined, these two HHS components have nullified the IRA non-duplication provision's protective guarantee. By the time a manufacturer must provide an MFP rebate, a covered entity will often not have even assessed whether it believes the relevant prescription is 340B-eligible, let alone told the manufacturer of that claim. Yet to avoid paying the MFP, CMS requires a manufacturer to come up with "documentation demonstrating the claim was 340B-eligible." CMS 2027 IRA Guidance at 230. That is simply not possible under the status quo. Without data indicating which units a covered entity claims are 340B eligible, manufacturers will face an untenable choice. Manufacturers can pay MFP rebates when claimed by a covered entity, fill the claiming covered entity's 340B product replenishment orders, and inevitably be subject to precisely the MFP-340B duplication that the IRA purports to protect against. Or manufacturers can deny MFP rebates when claimed by a covered entity that purchases significant volumes of 340B-priced product and face crippling civil monetary penalties because HHS has said that the 340B status of an MFP claimant alone is insufficient to support a claim of MFP-340B duplication. CMS 2027 IRA Guidance at 230.

64. Novartis will soon be forced into exactly this duplicate-discount scenario. CMS selected Novartis's heart-failure drug Entresto 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 2 (Aug. 2024) https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf. Novartis must therefore provide CMS with a written "plan for making the MFP available" for Entresto, called an MFP effectuation plan, by September 1, 2025. CMS 2027 IRA Guidance at 285. That plan should ensure the non-duplication provision's obligations *and* protections are both effectuated. And Novartis must know by June 2025 if it can launch its cash-rebate model so that it has time to gain experience with that model before the September 1 deadline and that experience can inform Novartis's MFP effectuation plan.

65. The inflation-rebate story is similar. Drugs subject to a 340B discount must be excluded from the rebate calculation. 42 U.S.C. § 1395w-3a(*i*)(3)(B)(ii)(I) (Medicare Part B); *id.* § 1395w-114b(b)(1)(B) (Medicare Part D). CMS, which calculates those rebates, has yet to come up with a way to do so as to Part D. Medicare and Medicaid Programs, 89 Fed. Reg. 97,710, 98,292–93 (Dec. 9, 2024) (noting that CMS "plan[s] to explore" a future solution). Nor will CMS conduct audits to detect duplication, *id.* at 98,248–49, or provide any "additional reporting," *id.* at 98,306. Thus, it is unclear how CMS will accomplish this important IRA objective given the unavailability of data to CMS and to manufacturers alike under the product-replenishment model.

Novartis's Intended Cash-Rebate Model

66. Novartis has found a solution to those problems in the 340B statute itself: a cash-rebate model. Like the model currently used for ADAPs, covered entities would first buy Novartis's medicines at commercial prices. After identifying a prescription as 340B-eligible, a covered entity would submit a 340B-rebate claim to Novartis electronically. Novartis would then pay the covered entity cash in an amount equal to the difference between the commercial price and the 340B price.

67. The cash-rebate model would provide Novartis the data it needs to ensure compliance with multiple overlapping statutory directives. Novartis's cash-rebate model would stop MDRP-340B duplication before it happens. Paired with the MFP cash-rebate model already authorized by CMS, Novartis would be able to determine which discount, if any, is required on a particular unit, and thus pay (or not pay, as appropriate) IRA MFPs correctly. Novartis also would be able to accurately calculate IRA inflation rebates. And, if necessary, Novartis would have sufficient information to audit noncompliant covered entities, restoring its access to statutory ADR proceedings.

68. Novartis's intended cash-rebate model is fully consistent with both the 340B statute and its PPA, both of which give Novartis the discretion to provide 340B prices using either rebates or discounts.

69. The cash-rebate model would apply to all of Novartis's 340B-price-eligible products. Novartis seeks to implement the cash-rebate model in June 2025 for Disproportionate Share Hospital (DSH) covered entities, where the most-significant abuse of the 340B Program has been observed.

70. Novartis must know whether it can launch its cash-rebate model by June 2025 in order to have sufficient experience to inform its MFP effectuation plan, which Novartis must submit by September 1, 2025.

71. Covered entities would submit data to validate that a prescription was eligible for 340B pricing. That data would include standard information that covered entities collect and maintain in the normal course of business.

72. Novartis intends to use the submitted data to identify 340B units for which state Medicaid programs have submitted rebate claims under the MDRP. Novartis would not deny

covered entities' 340B rebate claims based on MDRP-340B duplication. Novartis instead would use the submitted data to dispute the duplicate price concession claimed by state Medicaid programs under existing legal processes. In addition, where multiple DSH covered entities submit 340B rebate claims on the same unit, Novartis would work with the covered entities to determine the correct recipient.

73. Once a covered entity has submitted data to validate that it has dispensed enough 340B-eligible units to constitute a full package, Novartis would issue the covered entity a cash rebate within seven to ten days. For products with a single-unit package size, this payment would occur after each validated 340B prescription.

74. Novartis's intended 340B cash-rebate model would enhance operational efficiency, support compliance with statutory requirements, and facilitate timely access to 340B pricing.

HRSA's Refusal to Approve Novartis's Cash-Rebate Model and HRSA's Policy Regarding Cash-Rebate Models Generally

75. Novartis advised HRSA by letter in December 2024 that Novartis planned to implement its proposed cash-rebate model in June 2025. Novartis's letter also requested that HRSA acknowledge in writing Novartis's right to implement its intended 340B rebate model. Novartis explained that, if HRSA did not respond by January 7, 2025, Novartis would understand HRSA to have purported to disapprove the model, consistent with the agency's publicly stated position on the 340B rebate model more generally.

76. HRSA responded on January 14, 2025. HRSA stated that "the Secretary has not provided for . . . a rebate model" like Novartis's and, "[t]herefore, implementing such a model at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval of Novartis's proposed rebate model." Even though HRSA took the position

that Novartis's implementation of its cash-rebate model would violate the 340B statute, HRSA also stated that "[t]he Secretary has neither approved nor disapproved Novartis' rebate model."

77. HRSA's response was consistent with its letters to other manufacturers and consistent with the agency's publicly stated position on its website. HRSA has publicly and uniformly refused to allow other manufacturers to move forward with their cash-rebate models and has, in fact, threatened those manufacturers with draconian penalties if they moved forward. For instance, when Johnson & Johnson announced that it would implement a cash-rebate model similar to Novartis's, HRSA asserted that the model could not be implemented without HRSA preapproval. HRSA also warned Johnson & Johnson that, if the company implemented a cash-rebate model without HRSA's preapproval, HRSA could terminate Johnson & Johnson's PPA—and with it, the availability of federal funds under Medicaid and Medicare Part B for its products—as well as assess civil monetary penalties. Letter from HRSA to Johnson & Johnson (Sep. 17, 2024), https://www.hrsa.gov/sites/default/files/hrsa/opa/sept-17-2024-hrsa-letter-johnson-johnson.pdf, (J&J Letter).

78. Ten days later, HRSA escalated the threat, explaining that, if Johnson & Johnson did not comply with its demands, HRSA "*will* begin the process" of terminating its PPA and "*will*" refer Johnson & Johnson to the HHS Office of Inspector General. Letter from HRSA to Johnson & Johnson (Sep. 27, 2024), https://www.hrsa.gov/sites/default/files/hrsa/opa/sept-27-24-hrsa-letter-johnson-johnson.pdf (emphases added).

79. HRSA later made clear that this threat applies to all drug manufacturers. When Sanofi told covered entities of its intention to begin using a cash-rebate model, HRSA sent it a letter threatening to terminate Sanofi's PPA and impose civil monetary penalties. Letter from

HRSA to Sanofi (Dec. 13, 2024), https://www.hrsa.gov/sites/default/files/hrsa/opa/dec-13-2024-hrsa-letter-sanofi.pdf (Sanofi Letter).

80. HRSA published all three letters on its website. HRSA, *Program Integrity* (last updated Jan. 2025), https://www.hrsa.gov/opa/program-integrity. And if the letters' message were not already clear enough, HRSA's website includes an unequivocal legal position: "[I]mplementing a rebate proposal without Secretarial approval would violate Section 340B(a)(1) of the Public Health Service Act." HRSA, *340B Drug Pricing Program* (last updated Jan. 2025), https://www.hrsa.gov/opa.

81. HRSA's letters and policy on its website are 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" Public Health Service 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.

82. As HRSA's repeated letters and public statements show, it expects all drug manufacturers to comply with the agency's asserted preapproval power—or face severe penalties.

HRSA's Refusal to Approve Novartis's Cash-Rebate and HRSA's Policy Regarding Cash-Rebate Models Are Unlawful

83. HRSA's refusal to approve Novartis's intended 340B rebate model and HRSA's policy regarding cash-rebate models generally—published on HRSA's website—are unlawful.

Agency approval is not needed for Novartis to proceed with its cash-rebate model.

84. Novartis's intended 340B rebate model is consistent with both the 340B statute and its PPA. Under the statute, the PPA, and prior HRSA practice, agency approval is not needed for Novartis to implement its intended rebate model.

85. The text and legislative history of the 340B statute expressly contemplate that 340B pricing may be effectuated through either a discount or a rebate, with no preference for one or the other. 42 U.S.C. § 256b(a)(1), (2), (5)(A) (contemplating a "rebate" or "rebates"); H.R. Rep. No. 102-384(II), *16 (1992) ("The bill does not specify whether 'covered entities' would receive these favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism.").

86. HRSA has long acknowledged that flexibility. It admitted that "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. HRSA has also pointed to the legislative history for the conclusion that "section 340B does not specify whether entities should receive the section 340B pricing 'through a point of purchase discount, through a manufacturer rebate, or through some other mechanism.' " *Id.* (quoting H.R. Rep. No. 102-384(II), *16 (1992)).

87. Neither Novartis's PPA nor any regulation requires or prioritizes the use of a discount model or any other method for providing 340B prices.

88. Manufacturers are therefore free to effectuate 340B pricing through either a discount or a rebate, without agency preapproval.

HRSA's refusal to approve Novartis's cash-rebate model and HRSA's policy regarding cash-rebate models generally are arbitrary and capricious.

89. Even if HRSA's preapproval of a cash-rebate model were statutorily required, HRSA's refusal to preapprove Novartis's cash-rebate model and HRSA's policy regarding cash-rebate models generally are arbitrary and capricious for several reasons.

90. *First*, HRSA cannot require a manufacturer to offer 340B pricing when the manufacturer has no statutory obligation to do so. Yet HRSA's refusal to approve Novartis's cash-rebate model does just that by denying Novartis the tools to prevent unlawful duplication—unlawful duplication that the 340B statute absolves Novartis any obligation to provide 340B pricing for. The agency's decision similarly perpetuates the unlawful diversion inherent in the product-replenishment model.

91. *Second*, HRSA must treat like cases alike. But HRSA's refusal to approve Novartis's cash-rebate model fails to give Novartis's model the same treatment the agency has afforded to the cash-rebate model used by ADAPs even though there is no material difference between the two. Novartis's PPA, after all, does not purport to authorize Novartis to use a cash-rebate model for ADAPs. Nor did HRSA require manufacturers or ADAPs to obtain preapproval of the cash-rebate model they use.

92. HRSA has previously hinted at possible distinctions between the two models by mentioning the ostensibly "unique" needs of ADAPs. 63 Fed. Reg. at 35,241. Even if ADAPs' needs were unique when HRSA wrote that in 1998, it is no longer true today. As HRSA's current guidance manual for ADAPs recognizes, 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." ADAP Manual at 42. That is no longer a unique model: Other covered entities use the product-replenishment model in exactly that way, purchasing drugs at the market price and later reconciling that purchase with the 340B ceiling price. HRSA similarly noted that ADAPs implement the cash-replenishment model through "formal agreements with a network of retail pharmacies." *Id.* Other covered entities now do the same by using third-party contract pharmacies to dispense covered outpatient drugs and third-party administrators to assess 340B eligibility.

93. *Third*, HRSA may not treat Novartis's cash-rebate model differently than the current product-replenishment model because the product-replenishment model is just another form of a rebate model.

94. That 340B pricing in the product-replenishment model is currently implemented through an after-the-fact product rebate, rather than an after-the-fact cash rebate, is irrelevant because the 340B statute gives no basis to prefer one rebate form over the other. There is therefore no legitimate reason for objecting to Novartis's intended cash-rebate model on the ground that covered entities would not receive upfront 340B pricing on a 340B-eligible unit because the prevailing product-replenishment model operates in the same way.

95. Yet HRSA has subjected Novartis's cash-rebate model and the product-replenishment model to profoundly different treatments. HRSA contends that implementing a cash-rebate model without agency preapproval merits the harshest sanctions HRSA can impose. *See* J&J Letter at 1; Sanofi Letter at 1–2. But the product-replenishment model was implemented and currently functions without HRSA's approval. *See, e.g.*, HRSA, *340B Peer-to-Peer Program: 340B Compliance Improvement Guide* 36–37 (Oct. 1, 2015), https://www.hrsa.gov/sites/default/files/hrsa/opa/compliance-improvement-guide.pdf.

96. HRSA's differential treatment of the two models is particularly irrational because of the models' relative program-integrity merits. While the product-replenishment model significantly weakens 340B Program integrity by perpetuating unlawful Section 340B claims, Novartis's intended 340B rebate model would significantly enhance it. HRSA has no reasonable basis for tolerating the current slow, opaque, and abuse-ridden product-rebate model, while spurning faster, more-transparent, and more-compliant cash rebates. Indeed, one of HRSA's only bases for preferring the product-replenishment model is that covered entities that use that model "voluntarily

choose" to do so. J&J Letter at 2. But *covered entities'* preference for a model with more program-integrity concerns is hardly a rational reason for *HRSA* to prefer the model; in fact, it demonstrates that HRSA is treating two participants in the 340B Program—covered entities and manufacturers—differently for no rational reason.

97. *Fourth*, HRSA's rejection of Novartis's cash-rebate model impedes important statutory goals. The 340B statute forbids MDRP-340B duplication, but HRSA's lax oversight has failed to achieve that goal. HRSA cannot rationally reject Novartis's cash-rebate model when it is the only feasible method of fixing the current endemic MDRP-duplication problem.

98. The IRA similarly forbids MFP-340B duplication. But the product-replenishment model makes it impossible to identify 340B-eligible units in time to avoid duplication. Accordingly, Novartis's cash-rebate model is the only method for manufacturers to achieve this statutory mandate, too. HRSA's rejection of Novartis's cash-rebate solution is especially irrational because HHS has disclaimed any responsibility to ensure that the non-duplication provision's protection is effectuated. HHS cannot instruct drug manufacturers to comply with a statutory directive, refuse to provide any support, and then actually forbid the only viable solution that also guarantees the protection afforded by that same statutory mandate.

HRSA's refusal to approve Novartis's cash-rebate model and HRSA's policy regarding cash-rebate models generally deny Novartis substantive and procedural due process.

99. HRSA's refusal to approve Novartis's cash-rebate model and HRSA's policy regarding cash-rebate models generally unlawfully deprive Novartis of protected property interests without due process of law.

100. Novartis has a protected property interest in covered outpatient drugs that are subject to 340B pricing. The 340B and IRA statutes protect that property interest by each limiting the availability of 340B and MFP pricing in certain statutorily defined circumstances. *See* 42 U.S.C.

§§ 256b(a)(1), (a)(4); *id.* § 1320f-2(d). When Novartis is unlawfully compelled to provide its medicines at either MFP or 340B prices in those circumstances, Novartis is deprived of a protected property interest in its medicines.

101. Agency action that is so arbitrary as to shock the conscience violates a company's substantive-due-process rights, regardless of the procedure used to effect the deprivation. *See Al-Hela v. Biden*, 66 F.4th 217, 242 (D.C. Cir. 2023); *Estate of Phillips v. District of Columbia*, 455 F.3d 397, 403 (D.C. Cir. 2006).

102. HRSA's refusal to approve Novartis's cash-rebate model results in conscience-shocking arbitrariness because it subjects Novartis to irreconcilable HHS demands.

103. On the one hand, to correctly charge the lower of the 340B price or the MFP as the IRA mandates, HHS requires Novartis to discern whether a prescription is 340B-eligible—backed by documentation—within 14 days of receiving data showing that prescription has been dispensed. But HHS then admits that the data it will require dispensing entities to provide to Novartis to make that decision do not indicate whether a prescription is 340B-eligible. *See* 42 U.S.C. § 1320f-2(d); CMS 2027 IRA Guidance at 196, 202–04, 230. And HHS has declined to help Novartis figure that out on its own. *See* CMS 2027 IRA Guidance at 54–56, 232.

104. HHS's refusal, through HRSA, to approve Novartis's intended cash-rebate model prevents Novartis from implementing the only system that would allow Novartis to carry out HHS's instructions. As a result, Novartis must provide duplicate price concessions that, by law, it should not have to offer. And if Novartis does not accede, HHS will levy the most severe sanctions in its power. If Novartis were to use a cash-rebate model to get the data it needs, HHS would terminate Novartis's PPA—excluding it from the 340B Program and making its products ineligible for federal reimbursements under Medicare Part B and Medicaid—and seek additional civil

monetary penalties. If HHS were to successfully carry out its threat to impose civil monetary penalties, Novartis's potential liability would be immense, at up to $7,034 "for *each instance* of overcharging a covered entity that may have occurred." 42 U.S.C. § 256b(d)(1)(B)(vi)(II) (emphasis added); Annual Civil Monetary Penalties Inflation Adjustment, 89 Fed. Reg. 64,815, 64,819 (Aug. 8, 2024) (adjusting the statutory amount for inflation). If, instead, Novartis were to fail to pay MFP rebates timely, HHS would assess civil monetary penalties "equal to ten times the amount" of the (inadvertent) overcharges. 42 U.S.C. § 1320f-6(a).

105. HHS has therefore put Novartis in an irresolvable situation, which violates Novartis's substantive-due process rights.

106. In addition, agency action that deprives a company of a property interest without "a meaningful opportunity to be heard" is unconstitutional. *Propert v. District of Columbia*, 948 F.2d 1327, 1333 (D.C. Cir. 1991).

107. The 340B statute and its implementing regulations provide Novartis with an opportunity to be heard by allowing it to initiate ADR proceedings to redress instances where a covered entity has claimed a discounted 340B price incorrectly. *See* 42 U.S.C. § 256b(d)(3)(A); 42 C.F.R. § 10.21(a)(2).

108. But to access that opportunity, Novartis must first audit the covered entity. 42 U.S.C. § 256b(a)(5)(C); 42 C.F.R. § 10.21(a)(2). And under HRSA's current guidance, Novartis cannot audit a covered entity unless it can first amass "sufficient facts and evidence" to establish "reasonable cause" for believing that a covered entity has caused a 340B price to be paid incorrectly. Audit Guidance, 61 Fed. Reg. at 65,410. For those reasons, Novartis's opportunity to be heard regarding deprivations of its property interest in medicines subject to 340B pricing is conditioned on its having access to sufficient information to establish "reasonable cause."'

109. When a covered entity uses the product-replenishment model, Novartis typically does not have sufficient information about the entity's basis for claiming that a prescription was 340B-eligible to establish "reasonable cause" to challenge that determination. Novartis therefore cannot access one of its few avenues to be heard on claims that it has been erroneously deprived of a protected property interest.

110. If Novartis were to implement its proposed cash-rebate model, it would have sufficient information to confirm eligibility, allowing it to prevent unlawful deprivations from occurring in the first place. If necessary, Novartis would also have enough information to audit covered entities and to bring ADR claims following the audit, providing Novartis with opportunities to be heard that it currently lacks.

111. HHS's refusal, through HRSA, to approve Novartis's cash-rebate model and HRSA's general policy regarding cash-rebate models will also subject Novartis to extensive duplicate MFP-340B price reductions and impair Novartis's ability to avail itself of HHS's process for ensuring MFP-340B nonduplication. HHS permits a manufacturer that believes an improper MFP rebate has been claimed to deny the duplicate rebate, with the entity claiming the MFP rebate having the option to initiate a dispute process through CMS. CMS 2027 IRA Guidance at 218–19. But HHS requires that the manufacturer maintain documentation supporting its denial of the claimed MFP rebate. *Id.*

112. Without a cash-rebate model, it will be difficult for Novartis to obtain the data needed to substantiate a denial of a suspected MFP-340B duplicate rebate. And if Novartis's available documentation for a denied claim does not meet HHS's satisfaction, Novartis faces the potential of significant civil monetary penalties. The bottom line: Without a cash-rebate model,

Novartis can access the procedure HHS has provided it for disputing improper MFP-340B duplicate rebates only by risking crushing civil monetary penalties.

113. Moreover, without data indicating which units a covered entity claims are 340B eligible, which manufacturers typically do not receive under the product-replenishment model, a manufacturer has no way to determine whether it has already paid an MFP rebate on a replenishment unit for which the 340B price is claimed. As a result, not only can the manufacturer not withhold the MFP rebate or deny the 340B rebate (if the MFP is lower than the 340B price), it will not be able to mitigate the harm by paying only the difference between the MFP and the 340B price (if the MFP is higher than the 340B price). Instead, in addition to paying the MFP discount, the manufacturer will *also* pay the covered entity the difference between the market price and the 340B discount on the same unit.

114. By not approving Novartis's cash-rebate model and by promulgating its policy regarding cash-rebate models generally, HRSA has ensured that erroneous deprivations of Novartis's property interests will continue. And the agency has foreclosed any avenue to be heard—or, at least, made it materially more difficult for Novartis to be heard—regarding those deprivations.

115. Given the high volume of unlawful 340B discounts, Novartis is erroneously deprived of its property not occasionally, but routinely. *See* Mundra, *The 340B Noncompliance Data Gap*, *supra*. Those deprivations are unconstitutional because due process requires procedural protections to prevent, to the extent possible, the erroneous deprivation of property. *See Gilbert v. Homar*, 520 U.S. 924, 930–932 (1997).

116. Novartis has no other recourse to avoid these erroneous deprivations of its property interests. If Novartis were to implement its cash-rebate model despite HRSA's refusal to approve it and in the face of HRSA's general policy regarding the cash-rebate model, HRSA would

terminate Novartis's PPA and has threatened significant civil monetary penalties. HHS has also warned manufacturers that they can face significant civil monetary penalties if they deny MFP rebates without supporting documentation that meets HHS's satisfaction—documentation that manufacturers may not have without a cash-rebate model.

117. Those consequences would be financially ruinous. Medicare Part B represents a large share of the U.S. prescription-drug market, with over $30 billion in annual spending by 2021, and the "fastest rate of spending growth for drugs in the Medicare program." HHS, Office of the Assistant Secretary for Planning & Evaluation, *Medicare Part B Drugs: Trends in Spending & Utilization, 2008–2021* at 2–3, https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf. Medicaid likewise serves more than 72 million Americans. CMS, *August 2024 Medicaid & CHIP Enrollment Data Highlights* (last updated Nov. 27, 2024), https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/reporthighlights/index.html. Losing access to these programs would cause Novartis to lose an unsustainable amount of revenue, not to mention any additional financial harm wrought by civil monetary penalties under both the 340B statute and the IRA.

118. Moreover, Medicare Part B and Medicaid serve vulnerable patient populations. Novartis could not withdraw its products from those programs without depriving these patients of critical medicines, an untenable result.

119. Absent this Court's intervention, Novartis has no choice but to accept repeated erroneous deprivations of its property without any meaningful opportunity to be heard.

120. HRSA's refusal to approve Novartis's cash-rebate model and HRSA's policy regarding cash-rebate models generally therefore violate Novartis's procedural-due-process rights.

COUNT I
(Administrative Procedure Act—Contrary to Law and Exceeding Statutory Authority)

121. Novartis re-alleges and incorporates by reference the allegations in the foregoing numbered paragraphs.

122. The Administrative Procedure Act (APA) prohibits HRSA from carrying out the agency's statutory and regulatory duties in a manner that is unlawful, arbitrary, capricious, an abuse of discretion, or contrary to a constitutional right. *See* 5 U.S.C. § 706(2).

123. HRSA's refusal to approve Novartis's cash-rebate model and HRSA's policy regarding cash-rebate models generally disregard the 340B statute's text and history and Novartis's PPA. HRSA has therefore acted in excess of the agency's statutory authority and unlawfully under the APA.

124. The 340B statute allows manufacturers to implement 340B pricing through either a discount or a rebate. 42 U.S.C. §§ 256b(a)(1), (2), (5)(A). Novartis may therefore offer 340B pricing through either method, without agency preapproval.

125. HRSA's refusal to approve Novartis's cash-rebate model in its January 14, 2025 letter and HRSA's policy regarding cash-rebate models generally constitute final agency action for which Novartis has no other adequate remedy at law.

COUNT II
(Administrative Procedure Act—Arbitrary and Capricious)

126. Novartis re-alleges and incorporates by reference the allegations in the foregoing numbered paragraphs.

127. HRSA's refusal to approve Novartis's cash-rebate model and HRSA's policy regarding cash-rebate models generally are arbitrary and capricious, lack a logical basis, and constitute an abuse of discretion for at least four reasons. *See* 5 U.S.C. § 706(2)(A).

128. *First*, HRSA's decision and policy force Novartis to offer 340B pricing where it has no statutory obligation to do so.

129. *Second*, HRSA irrationally distinguished between the cash-rebate model that ADAPs have used for decades and the cash-rebate model Novartis intends to implement as to DSH covered entities, even though there are no material differences between those models. HRSA has also failed to reasonably explain that differential treatment.

130. *Third*, HRSA irrationally distinguished between Novartis's intended cash-rebate model and the product-replenishment rebate model used by most covered entities, even though there are no material differences between the two. Both models depend on the use of rebates, and HRSA has allowed the use of the product-replenishment model without preapproving it.

131. *Fourth*, HRSA's refusal to approve Novartis's cash-rebate model and HRSA's policy regarding cash-rebate models generally prevent the accomplishment of important statutory goals, including the prevention of MDRP-340B duplication, MFP-340B duplication, and accurate calculation of IRA inflation rebates.

132. HRSA's refusal to approve Novartis's cash-rebate model and HRSA's policy regarding cash-rebate models generally constitute final agency action for which Novartis has no other adequate remedy at law.

COUNT III
(Fifth Amendment—Substantive Due Process)

133. Novartis re-alleges and incorporates by reference the allegations in the foregoing numbered paragraphs.

134. The Fifth Amendment's Due Process Clause prohibits the government from depriving an 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. The APA also forbids agency action that is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

135. HHS's refusal, through HRSA, to approve Novartis's cash-rebate model and HRSA's policy regarding cash-rebate models generally result in conscience-shocking arbitrariness because they subject Novartis to irreconcilable HHS demands that Novartis cannot simultaneously meet.

136. HHS's refusal, through HRSA, to approve Novartis'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 under the APA.

COUNT IV
(Fifth Amendment—Procedural Due Process)

137. Novartis re-alleges and incorporates by reference the allegations in the foregoing numbered paragraphs.

138. The Fifth Amendment's Due Process Clause prohibits the federal government from depriving a company of a constitutionally protected property interest without following constitutionally sufficient procedures. The APA also forbids agency action that is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

139. The Due Process Clause requires notice and an opportunity to be heard "at a meaningful time and in a meaningful manner." *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965); *see also Mathews v. Eldridge*, 424 U.S. 319, 333 (1976). Procedural protections must also prevent as much erroneous deprivation of property as possible. *See Gilbert*, 520 U.S. at 930–932.

140. When Novartis is compelled to provide either the 340B price, the MFP, or both, when it has no statutory obligation to do so, it is deprived of a constitutionally protected property interest.

141. HRSA's refusal to approve Novartis's cash-rebate model and HRSA's policy regarding cash-rebate models generally deny Novartis the information it needs to access the 340B statute's audit and ADR procedures.

142. HRSA's refusal to approve Novartis's cash-rebate model and its policy regarding cash-rebate models generally make it difficult, if not impossible, to obtain the documentation necessary to support denials of improperly claimed MFP-340B duplicate pricing and risk depriving Novartis of access to HHS's MFP rebate dispute procedures and subjecting Novartis to significant civil monetary penalties.

143. Absent the ability to access the 340B statute's audit and ADR procedures, as well as HHS's MFP rebate-dispute procedures, Novartis has no meaningful opportunity to be heard regarding deprivations of its constitutionally protected property interests in its medicines subject to 340B pricing.

144. The risk of erroneous deprivation of Novartis's property interests arising from incorrect applications of the 340B statute is substantial, and erroneous deprivations occur routinely.

145. HRSA's refusal to approve Novartis's cash-rebate model and HRSA's policy regarding cash-rebate models generally are therefore unconstitutional under the Fifth Amendment and should be vacated and set aside under the APA.

PRAYER FOR RELIEF

For the foregoing reasons, Novartis prays for the following relief:

A. A declaration pursuant to 28 U.S.C. § 2201 that the agency's position regarding Novartis's intended 340B cash-rebate model is unlawful;

B. An order vacating and setting aside HRSA's refusal in its January 14, 2025 letter to approve Novartis's cash-rebate model;

C. An order vacating and setting aside HRSA's policy, published on its website, regarding cash-rebate models generally;

D. Injunctive relief barring Defendants and any entities acting in concert with them from initiating or pursuing any enforcement actions against Novartis in connection with its 340B cash-rebate model;

E. An order awarding Novartis its costs, expenses, and attorney's fees incurred in these proceedings pursuant to 28 U.S.C. § 2412; and

F. Such other and further relief as the Court deems just and proper.

Respectfully submitted,

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