IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHNSON & JOHNSON HEALTH CARE SYSTEMS INC.,
1000 US Highway 202 South
Raritan, NJ 08869,

Plaintiff,

v.

XAVIER BECERRA, in his official capacity, and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, DC 20201,

and

CAROLE JOHNSON, in her official capacity, and HEALTH RESOURCES AND SERVICES ADMINISTRATION,
5600 Fishers Lane
Rockville, MD 20857,

Defendants.

Civil Action No. 1:24-cv-3188

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. In 1992, Congress enacted the federal 340B Drug Pricing Program ("340B Program") with the important goal of helping uninsured and indigent patients gain greater access to reduced-cost medications. But more than thirty years later, the 340B Program is being regularly abused by entities it was never intended to benefit. Over time, the program has strayed far from its original aim and transformed into the second-largest federal drug program in the United States, smaller only than Medicare. Instead of supporting uninsured or indigent patients, it now primarily benefits sophisticated, well-resourced hospital systems and major for-profit retail pharmacy chains and their affiliated pharmacy benefit managers ("PBMs"). A lack of transparency has also subjected the program to rampant abuse, to the detriment of patients.

2. Plaintiff Johnson & Johnson Health Care Systems Inc. ("J&J") has been a proud participant in the 340B Program for more than three decades. J&J is committed to the 340B Program as it was originally intended: to assist vulnerable patients. This case is about J&J's efforts to bring much-needed transparency to the 340B Program today. An expedited adjudication of J&J's right to proceed with this initiative—which J&J has temporarily halted, pending resolution of these issues—is essential to preserving the integrity of a sustainable 340B Program and to ensuring that patients in need receive the benefits Congress intended.

3. In enacting the 340B Program, Congress permitted a small, narrowly-defined set of providers who treat significant numbers of low-income or indigent patients to receive substantial discounts when purchasing outpatient prescription medications. By its terms, the 340B statute, 42 U.S.C. § 256b, requires manufacturers of outpatient drugs to enter into an agreement with the U.S. Department of Health and Human Services ("HHS"), known as a Pharmaceutical Pricing Agreement ("PPA"), under which the manufacturer must offer reduced prices to specific categories

of providers specified in the statute. Entry into the PPA is required for a manufacturer's products to receive reimbursement under Medicare Part B and "Federal Financial Participation" under state Medicaid programs.

4. The 340B statute makes clear on its face that manufacturers may effectuate the 340B price for covered entities through varying mechanisms, including both upfront discounts and post-purchase rebates. In relevant part, the statute directs that, in the PPA, each manufacturer and HHS must agree that "the amount required to be paid (taking into account *any rebate or discount*, as provided by the Secretary) to the manufacturer for covered outpatient drugs . . . [will] not exceed" the "ceiling price." 42 U.S.C. § 256b(a)(1) (emphasis added). The PPA, a form agreement promulgated by Defendants, neither mandates nor prohibits manufacturer use of a particular pricing mechanism.

5. Exercising its discretion to select a mechanism for offering 340B prices, on August 23, 2024, J&J announced that it intended to shift from utilizing the current pricing model to using a limited-scope rebate model beginning on October 15, 2024 (the "Rebate Model"). J&J announced that its Rebate Model would apply at implementation to just two of J&J's drugs and to purchases by just one type of 340B covered entity—disproportionate share hospitals ("DSH" covered entities). J&J's Rebate Model does not change the universe of 340B-eligible transactions or the amount of the ceiling price offered for either drug.

6. DSH covered entities include some of the largest, most financially robust, and administratively sophisticated hospitals in the country. Although DSH covered entities today account for less than 10% of all covered entities, they are responsible for nearly 78% of all 340B purchases, and many of them report billions of dollars in annual revenue. Between early 2021 and mid-2024, purchases by DSH covered entities of J&J's 340B products grew 66%, while purchases

by all covered entities of J&J's 340B products increased 46%—despite the fact that, between 2013 and 2021, the size of the vulnerable patient population *declined* by half.

7. J&J's Rebate Model would not apply to covered entities other than DSH entities, such as federally qualified health centers, rural referral centers, sole community hospitals, critical access hospitals, and various other types of clinics and federal grant recipients.

8. J&J's Rebate Model responds to significant, well documented deterioration in the integrity of the 340B Program over the past several years. Despite Congress's good intent in 1992, the reality is that today's 340B Program is *not* operating consistent with that intent. Instead, the 340B Program has been overtaken by for-profit entities, including the nation's largest pharmacy chains and PBMs, who have exploited the Program for profit. Numerous reports by government watchdogs have found that covered entities are reaping immense profits on reduced-price medications—but failing to pass along those discounts to patients.

9. At the same time, the Health Resources and Services Administration ("HRSA"), the sub-agency within HHS that administers the 340B Program, has conducted hundreds of audits demonstrating that a substantial proportion of covered entities were non-compliant with provisions in the 340B statute that prohibit program abuse. These provisions bar covered entities from obtaining the 340B price on the same drug purchase that receives a Medicaid rebate (known as a "duplicate discount") or "diverting" 340B-priced drugs to individuals who are not their patients. For example, of 1,242 audits that HRSA conducted of covered entities between 2012 and 2019, HRSA made 546 findings of diversion and 429 findings relating to duplicate discounts with the Medicaid program.

10. J&J's own efforts to conduct HRSA-approved audits of covered entities have been thwarted. Although J&J received HRSA approval to audit 11 covered entities earlier this year,

almost all of these covered entities have defied HRSA's approval. Rather than participating in the audits, numerous covered entities first sought rescission of the audit approvals from HRSA and then refused to produce their records, in direct violation of their statutory obligations. Several covered entities have taken the unprecedented step of filing suit in this district challenging HRSA's approvals of J&J's audits. The limited nature of manufacturer audits generally raises questions about their ability to combat overall program abuse at its current scale. Obstruction has rendered even this limited mechanism effectively unavailable.

11. J&J's Rebate Model is necessary to ensure the integrity of the 340B Program, by more comprehensively providing the transparency sought through the audit process. The model would address the realities of today's healthcare delivery systems, in which access to real-time data is essential to manufacturers and other 340B Program stakeholders. For example, the Rebate Model would mitigate duplicate discounting between 340B purchases and rebates sought on the same medicines by various other downstream customers, in violation of the 340B statute. Moreover, the Rebate Model is the only mechanism J&J is currently aware of that would enable J&J to meet its statutory obligation under the Inflation Reduction Act ("IRA"). The IRA requires J&J to offer covered entities the lower of the 340B ceiling price or the IRA's "Maximum Fair Price" ("MFP") on applicable drugs, and to transmit the MFP to dispensing entities within 14 days. J&J needs real-time data identifying 340B-dispensed drugs in order to determine whether MFP or 340B pricing applies to each prescription claim and to transmit funds within the 14 days required by the Centers for Medicare & Medicaid Services ("CMS"). The Rebate Model would thus enable J&J to comply with the IRA's prohibition of duplicate discounts across the MFP and the 340B ceiling price.

12. J&J's Rebate Model is similar to the so-called "replenishment models" covered entities currently use for 340B purchasing. Under replenishment models, covered entities and their contract pharmacies purchase drug units at wholesale acquisition cost and then realize the 340B price only after placing orders at the 340B-reduced price to "replenish" the pharmacy's stock. Although the 340B statute is silent on replenishment models, HRSA has acquiesced to their widespread use by covered entities, without ever asserting that the agency's permission was required or issuing an explanatory guidance document setting forth the basis for its approval. Notably, replenishment models act materially the same as rebate models, allowing the 340B discount to be effectuated after the initial sales transaction.

13. Notwithstanding the permissibility of J&J's Rebate Model under the 340B statute and the substantial program integrity benefits that the Rebate Model will provide, HRSA informed J&J in letters sent on August 14, 2024 (the "August 14 Letter"), September 17, 2024 (the "September 17 Letter"), and September 27, 2024 (the "September 27 Letter") that (a) the HHS Secretary has discretion over whether to approve J&J's Rebate Model; (b) the Secretary has not given such approval for J&J's Rebate Model; (c) if J&J proceeds with implementing its Rebate Model without HRSA approval, it would violate the 340B statute; and (d) absent J&J informing HRSA by September 30, 2024 that it would cease implementation of its Rebate Model, HRSA would impose draconian sanctions, including referring J&J for imposition of substantial civil penalties and terminating J&J's PPA, depriving 340B, Medicaid, and Medicare patients of access to all of J&J's medicines—not just the products subject to the Rebate Model.

14. The August 14 Letter, September 17 Letter, and September 27 Letter, which announce HRSA's definitive interpretation of the 340B statute, are final agency actions that are arbitrary and capricious and contrary to law. The 340B statute does not authorize HRSA to

mandate through a letter that manufacturers must use a specific mechanism for effectuating the 340B price. To the contrary, to the extent HRSA has authority to direct a pricing mechanism at all, the plain text of the 340B statute requires that it do so *only* through the PPA. Because J&J's PPA contains no such direction or requirement, J&J as a matter of law retains full discretion to utilize the pricing mechanism of its choice.

15. The September 17 Letter also wrongly asserts that J&J's Rebate Model would violate the 340B statute by requiring DSH covered entities to purchase J&J's medicines "at prices that exceed 'the maximum price[s] that covered entities may permissibly be required to pay' for those drugs." That conclusion ignores that the 340B statute—on its face—recognizes rebates as a mechanism for effectuating the 340B price and that rebates, by definition, involve transactions with an initial cost that is higher than the actual price paid after the rebate is applied.

16. On September 30, 2024, J&J notified HRSA that, because of HRSA's threats to terminate J&J's PPA, J&J had no choice but to forgo implementation of the Rebate Model pending resolution of these issues. Absent HRSA's threats of severe and disproportionate sanctions, including termination of J&J's PPA, J&J would have proceeded with the Rebate Model as announced on October 15, 2024.

17. The Rebate Model that J&J intends to launch represents a limited but significant step toward remedying the dysfunction and abuse that pervades today's 340B Program. Neither the universe of eligible 340B claims nor the amount of the 340B price to DSH covered entities would change. Instead, DSH covered entities would receive rebates effectuating the 340B price within seven to ten days from when they provide data confirming the purchase and dispense.

18. HRSA's threats to seek civil monetary penalties ("CMPs") and terminate J&J's PPA are grossly disproportionate to the impact of J&J's modest proposal to offer (the same) deeply

discounted prices to one category of 340B covered entities through a commercially-standard rebate. Termination of J&J's PPA would mean that millions of the country's most vulnerable patients who rely on Medicaid and Medicare for healthcare would be denied access to *all* J&J medicines—including medicines that treat cancer, mental illness and other serious and life-threatening diseases.

19. HRSA's attempts to bar J&J from bringing transparency to the 340B Program through implementation of the Rebate Model are fundamentally at odds with the 340B statute, the Administrative Procedure Act, and HRSA's own stated program integrity goals. They are also entirely inconsistent with the approach that HRSA has taken regarding the replenishment models that covered entities unilaterally implemented more than a decade ago, even though replenishment models have many of the same features and operate in materially the same manner as J&J's proposed Rebate Model. The Court should declare that HRSA's August 14, September 17, and September 27 letters purporting to prohibit J&J from adopting the Rebate Model are unlawful; set the letters aside; and enjoin Defendants from commencing any enforcement action against J&J relating to or arising from the implementation of the Rebate Model.

JURISDICTION AND VENUE

20. This action arises under, and asserts violations of, the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 *et seq*., and Section 340B of the Public Health Service Act, 42 U.S.C. § 256b. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1346. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other appropriate relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and the APA, 5 U.S.C. §§ 705-06.

21. HRSA's determinations in its August 14 Letter, September 17 Letter, and September 27 Letter that J&J's Rebate Model violates the 340B statute, and that HRSA has discretion to mandate a 340B pricing mechanism through a procedure other than a PPA amendment, are final agency actions that are inconsistent with the statute's plain text and subject to judicial review under the APA. *See* 5 U.S.C. §§ 704, 706.

22. Venue is proper in this Court under 28 U.S.C. § 1391(e)(1) because this action seeks relief against federal agencies and officials acting in their official capacities; at least one defendant is located in this district; and a substantial part of the events or omissions giving rise to the claim occurred in this district.

PARTIES

23. Plaintiff J&J is a New Jersey corporation with its principal place of business in Raritan, New Jersey. J&J has participated in the 340B Program for more than thirty years.

24. Defendant Xavier Becerra is the Secretary of HHS. He has ultimate responsibility for oversight of the activities of HRSA, including with regard to the administration of the 340B Program and the actions complained of herein. He is being sued in his official capacity. Secretary Becerra maintains an office at 200 Independence Avenue, S.W., Washington, DC 20201.

25. Defendant HHS is an executive department of the United States government that is responsible for HRSA and the 340B Program. HHS is headquartered in Washington, D.C.

26. Defendant Carole Johnson is the Administrator of HRSA. She is being sued in her official capacity. Administrator Johnson maintains an office at 5600 Fishers Lane, Rockville, MD. Administrator Johnson, among other duties, has ultimate responsibility for HRSA's Office of Pharmacy Affairs and its administration of the 340B Program.

27. Defendant HRSA is an administrative agency of the United States government within HHS. It is the division of HHS charged with administering the 340B Program. HRSA is headquartered in Rockville, Maryland.

FACTUAL ALLEGATIONS

The Federal 340B Program Caps Drug Prices for Certain Covered Entities that Provide Healthcare to Underserved Populations

28. Section 340B of the Public Health Service Act establishes a federal program that "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities," known as covered entities, that provide healthcare to certain underserved populations. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011).

29. Section 340B defines "covered entity" to include 15 carefully drawn and narrow categories of healthcare providers, including distinct parts of specified types of hospitals and recipients of certain federal grants. 42 U.S.C. § 256b(a)(4)(A)-(O).

30. Among these categories of healthcare providers are DSH covered entities. A DSH covered entity is a hospital that satisfies all three of the following criteria: (i) it "is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act . . . or eligible for [certain] assistance under the [Public Health Service Act]"; (ii) "for the most recent [Medicare] cost reporting period that ended before the calendar quarter involved, [it] had a disproportionate share adjustment percentage (as determined under [42 U.S.C. § 1395ww(d)(5)(F)]) greater than 11.75 percent or was described [at 42 U.S.C. § 1395ww(d)(5)(F)(i)(II)]"; and (iii) it "does not obtain covered outpatient drugs through a group

purchasing organization or other group purchasing arrangement." 42 U.S.C. § 256b(a)(4)(L). DSH covered entities are typically large, sophisticated hospital systems that can generate billions of dollars in revenue. They employ thousands or tens of thousands of people and utilize complex data systems, including for billing.

31. A pharmaceutical manufacturer must enter into a PPA with HHS for its products to receive reimbursement under Medicare Part B and for a state Medicaid program to receive "Federal Financial Participation" for the manufacturer's products. *See* 42 U.S.C. § 256b(a)(1). Under the PPA, a manufacturer must, among other things, "offer each covered entity covered outpatient drugs for purchase" at a specified discount price "if such drug is made available to any other purchaser at any price." *Id.* This is known as Section 340B's "must-offer" requirement.

32. Congress enacted Section 340B in 1992 to address an unintended consequence of the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388. Among other things, the 1990 Act established the Medicaid Drug Rebate Program, which altered pricing rules that had previously enabled some manufacturers to voluntarily provide lower prices on their drugs to safety net providers. The 340B Program restored the pre-1990 status quo, making the pre-1990 prices available again to covered entities but now exempting those lower prices from impacting the manufacturer's rebate obligations under the Medicaid rebate program. *See* H.R. Rep. No. 102-384, pt. 2, at 10-12 (1992) (House committee report explaining that the 340B Program would "remove any disincentive that the Medicaid rebate program creates to discourage manufacturers from providing substantial voluntary or negotiated discounts to these clinics, programs, and hospitals").

33. Over time, however, covered entities realized that they could take advantage of the 340B Program to generate "revenue from serving insured patients: they turn a profit when

insurance companies reimburse them at full price for drugs that they bought at the 340B discount." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023); *see Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 457 (D.C. Cir. 2024) (covered entities generate revenue from the "spread between the discounted price and the higher insurance reimbursement rate"). In other words, covered entities benefit from the spread between a 340B drug's acquisition cost (*i.e.*, the discounted 340B price) and negotiated rate at which insurance companies reimburse for the product (*i.e.*, a commercial rate likely approximate to the undiscounted list price). Eligibility to purchase drugs at 340B prices thus confers an extremely valuable benefit on covered entities, who have "a financial incentive to catalog as many prescriptions as possible as eligible for [a 340B] discount." *Novartis*, 102 F.4th at 457-58. Put simply, what was intended as a buy-low/sell-low program for vulnerable patients has turned into a buy-low/sell-high commercial business opportunity disconnected from its public health mission. This is the opposite of how charity care should be funded: the 340B Program creates incentives to provide services to *insured* patients rather than those vulnerable populations most in need of affordable care. *See, e.g.*, Rory Martin et al., IQVIA, *Unintended Consequences: How the Affordable Care Act Helped Grow the 340B Program* 5 (Aug. 30, 2024) (*Unintended Consequences*), https://bit.ly/3XFDWh8.

34. In enacting Section 340B, Congress sought to balance its goal of increasing patient access against the need to "assure the integrity of the drug price limitation program." H.R. Rep. No. 102-384, pt. 2, at 16. To that end, the 340B statute limits 340B pricing in two important respects. First, covered entities may not obtain 340B pricing on units of drugs that are also subject to the payment of a rebate under Medicaid (known as a "duplicate discount"). 42 U.S.C. § 256b(a)(5)(A). Second, covered entities may not resell or otherwise transfer 340B drugs to a person who is not a patient of the covered entity (known as "diversion"). *Id.* § 256b(a)(5)(B). A

covered entity that "knowingly and intentionally" engages in diversion must pay monetary penalties. *Id.* § 256b(d)(2)(B)(v)(I).

35. In addition, the 340B statute authorizes HRSA and manufacturers to conduct audits of covered entities' compliance with the diversion and duplicate discounting prohibitions:

> A covered entity *shall permit the Secretary and the manufacturer* of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

Id. § 256b(a)(5)(C) (emphasis added). As the text makes clear, covered entities have a statutory duty to comply with such audits.

36. In addition to regulating covered entities, the 340B statute also provides HRSA with the ability to take enforcement action against manufacturers who are found not to be complying with program requirements. Manufacturers that "knowingly and intentionally charge[] a covered entity a price for purchase of a drug that exceeds the [340B ceiling price]" are subject to CMPs. *Id.* § 256b(d)(1)(B)(vi)(III). The amount of the penalty is decided on a case-by-case basis, with a maximum of "$5,000 for each instance of overcharging," *id.* § 256b(d)(1)(B)(vi)(II), an amount that has been administratively adjusted for inflation up to the current maximum of $6,813. 88 Fed. Reg. 69,531, 69,535 (Oct. 6, 2023). HRSA has interpreted the phrase "instance of overcharging" to mean "any order for a covered outpatient drug, by NDC [a unique product identifier for each prescription drug product], which results in a covered entity paying more than the [340B] ceiling price." 42 C.F.R. § 10.11(b). In addition, "[e]ach order for an NDC will constitute a single instance, regardless of the number of units of each NDC ordered." *Id.* § 10.11(b)(1). HRSA initiates a CMP action by issuing a referral to HHS's Office of the Inspector

General, which has been delegated the HHS Secretary's authority to assess CMPs. 42 C.F.R. § 1003.150.

The 340B Statute Allows Manufacturers to Select the Mechanism for Offering Reduced-Priced Drugs to Covered Entities

37. The 340B statute directs the HHS Secretary to "enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account *any rebate or discount*, as provided by the Secretary) to the manufacturer for covered outpatient drugs . . . does not exceed" the "ceiling price." 42 U.S.C. § 256b(a)(1) (emphasis added). The statute on its face thus contemplates both "rebate[s]" and discount[s]" as options for furnishing the 340B price to covered entities, *id.*, and does not specify which mechanism manufacturers must use. Likewise, the PPA—the "agreement" referred to in the statute—does not address the pricing mechanism to be used.

38. To date, manufacturers participating in the 340B Program have offered the 340B price largely through a discount process. Broadly speaking, manufacturers supply their products to wholesalers at the wholesale acquisition cost ("WAC"); wholesalers then resell the drugs to covered entities at 340B prices; and wholesalers subsequently invoice the manufacturer for the difference between the WAC and the 340B price.

39. From its original enactment, the 340B statute was understood as affording manufacturers reasonable discretion over how best to make 340B-discounted prices available to covered entities. In 1992, the House Energy and Commerce Committee issued a report on a bill that became part of the Veterans Health Care Act of 1992 ("VHCA"), Pub. L. 102-585, 106 Stat. 4943, which established the 340B Program. H.R. Rep. No. 102-384, pt. 2 (1992). The report made clear that the legislation contemplated manufacturers using different mechanisms, including rebates, for providing 340B pricing to covered entities. The Committee noted this point multiple

times, explaining that "manufacturers, as a condition of receiving Federal Medicaid matching funds on their covered outpatient drugs, would have to enter into an agreement with the Secretary of HHS to provide price reductions (*whether through a discount, rebate, or other mechanism*) to these 'covered entities' on covered outpatient drugs." *Id.* at 12 (emphasis added); *see id.* at 16 ("The Committee 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.").

40. In addition to the House report, the Senate sponsor of the legislation explained in a floor speech that the bill would require manufacturers to enter agreements "to provide rebates or discounts" to covered entities. 138 Cong. Rec. 34279, 34293 (1992) (statement of Sen. Alan Cranston); *see id.* at 34294 (repeatedly referring to provisions addressing "rebate or discount agreement[s]" and "duplicate rebates and discounts"). These remarks confirm what the statute's plain text already makes clear: Congress intended to establish rebates as an acceptable mechanism through which manufacturers could offer the 340B price to covered entities, providing manufacturers commercial flexibility in administering the program.

41. Guidance issued a few years later makes clear that HRSA similarly understood that the 340B statute's pricing mechanism allowed for the use of rebates. In 1997, HRSA proposed guidance recognizing a rebate option for extending 340B pricing to State AIDS Drug Assistance Programs ("ADAPs"), a category of covered entity. 62 Fed. Reg. 45,823 (Aug. 29, 1997). The proposed guidance relied on the 1992 committee report to confirm HRSA's understanding 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.* at 45,824 (quoting H.R. Rep. No. 102-384, pt. 2, at 16). HRSA's final guidance, issued the

following year, confirmed that HRSA was not "propos[ing] a specific mechanism for accessing [340B] rebates" in order to "allow maximum flexibility between a State ADAP and manufacturers in the development of contracts and agreements." 63 Fed. Reg. 35,239, 34,239, 35,241 (June 29, 1998).

42. In 2010, as part of the Affordable Care Act, Congress amended Section 340B in several respects, including by adding language providing that each PPA must "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." 42 U.S.C. § 256b(a)(1). But this language was not intended to, and did not, eliminate rebates as a permitted mechanism for "offering" drugs for purchase at 340B prices. In particular, Congress did not remove or alter the preexisting statutory language that HRSA had read as allowing the use of rebates as a mechanism for offering 340B prices. *See id.* (retaining the "rebate or discount" language as first sentence of subparagraph). That language remains unchanged to the present day. And, to this day, HRSA guidance permits rebate models with respect to ADAPs.

The 340B Program Has Experienced Rampant Growth and Abuse

43. Since its inception in 1992, the 340B Program has expanded dramatically, becoming the second-largest federal prescription drug program in the country. The 340B Program has also changed considerably over time. Among other things, 340B entities have entered into so-called "contract pharmacy" arrangements, under which 340B covered entities "contract with outside pharmacies" for the distribution of 340B-discounted drugs. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 455 (D.C. Cir. 2024). Because pharmacy patients or their insurers often pay full price for drugs purchased at contract pharmacies, the arrangement enables the generation of revenue—which is shared by for-profit pharmacies, PBMs and covered entities—from the

"spread between the discounted price and the higher insurance reimbursement rate." *Id.* at 457. Covered entities' use of these "contract pharmacies" has exploded over time; between 2010 and 2019, the number of contract pharmacies dispensing 340B drugs ballooned from 1,300 to 23,000. U.S. Gov't Accountability Off., GAO-20-212, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* 2 (Jan. 27, 2020) (2020 GAO Report), https://bit.ly/3ZG0ctH. The contract pharmacy industry is now dominated by a handful of multi-billion dollar for-profit pharmacy chains and PBMs, including CVS Health, Walgreens, Cigna (via Express Scripts), UnitedHealth Group (via OptumRx), and Walmart. Adam Fein, *EXCLUSIVE: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market*, Drug Channels (July 11, 2023), https://bit.ly/3ZH23yG.

44. Because the number of uninsured patients has declined over time, it is more likely that patients prescribed drugs by 340B covered entities often have insurance, which could include Medicare, Medicaid, TRICARE or commercial insurance. Until there is a mechanism to identify 340B eligible patients in real time—which a rebate model would provide—manufacturers may pay duplicate discounts on the same unit: a 340B discount to a covered entity on the upfront sale and a back-end rebate to the patient's insurer.

45. As a result of these and other significant changes within the 340B Program, program abuse has also become rampant. There is a substantial and growing body of documented evidence of diversion or duplicate discounting by covered entities in violation of the 340B statute. Such abuses of the 340B Program threaten the Program's integrity and should be of great concern for all stakeholders.

46. For example, in 2020, the U.S. Government Accountability Office ("GAO") found that, of 1,242 audits that HRSA conducted of covered entities from fiscal years 2012 through 2019,

HRSA made 546 findings of diversion and 429 findings relating to duplicate discounts with the Medicaid program. U.S. Gov't Accountability Off., GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements* 13 (Dec. 14, 2020), https://bit.ly/4dniPpD. In other words, nearly 35% of HRSA's audits during that time period resulted in a finding of duplicate discounting, and 44% resulted in a finding of diversion.

47. Audits that HRSA has conducted more recently show that this trend has not abated. Indeed, out of the 198 audits HRSA conducted in fiscal year 2022 and has finalized to date, HRSA discovered at least 28 covered entities with instances of duplicate discounts, as well as evidence that nearly two dozen covered entities had diverted 340B drugs. *See* HRSA, *Program Integrity: FY22 Audit Results*, https://bit.ly/4ekBOlN (last updated Oct. 28, 2024). Likewise, out of the 161 audits HRSA conducted in fiscal year 2023 and has finalized to date, HRSA discovered at least 25 covered entities with instances of duplicate discounts, as well as evidence that more than a dozen covered entities had diverted 340B drugs. *See* HRSA, *Program Integrity: FY23 Audit Results*, https://bit.ly/4dpSxTs (last updated Oct. 28, 2024). These findings are particularly troubling given that HRSA audits fewer than 2% of covered entities on an annual basis, meaning the full scope of program abuse is likely even greater than HRSA's findings demonstrate.

48. Moreover, HRSA has only limited capabilities to detect and address covered entity noncompliance with the 340B statute through its audit processes. For example, HRSA's audits of covered entities do not assess all potential duplicate discounts because they focus only on Medicaid fee-for-service arrangements and do not include a review of Medicaid managed care claims. U.S. Gov't Accountability Off., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 39 (June 2018) (2018 GAO

Report), https://bit.ly/3N0XHdX. As a result, "manufacturers are at risk of being required to erroneously provide duplicate discounts for Medicaid prescriptions." *Id.* at 40.

49. The fact that HRSA does not assess potential duplicate discounting on Medicaid managed care claims is particularly concerning given the growth in states' usage of Medicaid managed care models over time. Today, 33 states and the District of Columbia utilize a managed care model *only*, and 74% of all Medicaid beneficiaries nationwide receive their care through managed care organizations ("MCOs"). Elizabeth Hinton & Jada Raphael, Kaiser Family Found., *10 Things to Know About Medicaid Managed Care* (May 1, 2024), https://bit.ly/3zJSzbm. In other words, HRSA's audits do not reach the vast majority of Medicaid claims, thereby leaving manufacturers without a key protection against this statutory violation.

50. GAO found similar risks in a 2020 report. Noting the expansion of both the 340B Program and the Medicaid Drug Rebate Program, GAO explained that the potential for duplicate discounts has increased significantly. 2020 GAO Report at 2. Despite that risk, GAO found that "HRSA's audits do not provide the agency with reasonable assurance that covered entities are taking the necessary steps to prevent duplicate discounts," putting manufacturers "at risk of being required to erroneously provide duplicate discounts for Medicaid drugs." *Id.* at 25.

51. CMS also has not taken sufficient action to address duplicate discounting. In its recent final rule implementing the Medicaid Drug Rebate Program, CMS required states to direct their Medicaid MCOs to use Medicaid-specific group numbers for all Medicaid beneficiaries. 89 Fed. Reg. 79,020, 79,026-29 (Sep. 26, 2024). Currently, MCOs may use the same group identifiers for both their Medicaid and commercial plans, making it difficult to distinguish between these patients. CMS noted that this change "may help States and their managed care plans avoid invoicing for rebates on 340B drugs by identifying which plans are covered under Medicaid." *Id.*

at 79,029. However, this step does not go far enough to solve for the risk of duplicate discounts. CMS affirmatively rejected suggestions to require pharmacies to use the identifiers to flag a specific claim as Medicaid-reimbursed and declined to require claims-level identifiers that would show in real time whether a unit dispensed under Medicaid was purchased under the 340B Program. *Id.* at 79,028-29. In other words, although MCOs will be required to identify their plans through a unique group identifier, covered entities still will not be required to identify units purchased at the 340B price for such Medicaid MCO utilization. CMS acknowledged that its proposal "will not fully address the risk of 340B duplicate discounts in Medicaid managed care." *Id.* at 79,028. Yet the agency asserted that any further policies to mitigate duplicate discounting risk were "outside of the scope of this final rule." *Id.* at 79,029. Thus, the risk of duplication between a 340B discount and a Medicaid rebate payment on the same unit of drug will persist, notwithstanding the new CMS regulation.

The Emergence of Replenishment Models Exacerbates These Issues and Further Undermines Program Integrity

52. These issues and abuses have been aggravated and magnified by the development of new technology systems and capabilities that covered entities have used to change their 340B Program operations. Most prominently, more than a decade ago, covered entities began to purchase drugs through the use of so-called "replenishment models" in which covered entities and their contract pharmacies make the initial purchase of a product at its (non-discounted) commercial price, dispense the product to an individual who is later determined to be a patient of the 340B entity, and then receive a replacement unit at 340B-discounted prices to "replenish" the pharmacy's stock. *See Novartis Pharms.*, 102 F.4th at 457-58 (describing operation of replenishment models); *see also* Decl. of Krista M. Pedley ¶¶ 5-9, *Sanofi-Aventis U.S., LLC v.*

HHS, No. 3:21-cv-634 (D.N.J. June 24, 2021) (Pedley Decl.), ECF No. 93-2 (HRSA description of replenishment models).

53. The D.C. Circuit recently described replenishment models as follows:

> The mechanism for distributing covered drugs [under the 340B Program] also has evolved. While some contract pharmacies maintain separate inventories of section 340B drugs, most fill prescriptions from inventories that intermingle discounted and non-discounted drugs. Only after dispensing the drugs do these pharmacies attempt to discern whether individual customers were patients of covered entities—in other words, whether individual prescriptions were eligible for the discount. Many pharmacies outsource this determination to third-party administrators, who often receive a larger fee for every prescription deemed eligible for the discount. Once the pharmacy or the administrator categorizes a certain number of prescriptions as eligible, the pharmacy places an order to replenish its section 340B purchases. The covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate. Each of these actors thus has a financial incentive to catalog as many prescriptions as possible as eligible for the discount.

Novartis Pharms., 102 F.4th at 457-58. Thus, replenishment models work after-the-fact, to reconcile transactions made initially at a commercial price to the 340B discount, analogous to a rebate mechanism.

54. HRSA has acknowledged the widespread usage of replenishment models in litigation. *See* Pedley Decl. ¶¶ 5-9, *Sanofi-Aventis U.S.*, No. 3:21-cv-634 (D.N.J. June 24, 2021), ECF 93-2. However, HRSA has never affirmatively authorized covered entities to utilize replenishment models, nor has it undertaken any process to assess and approve or reject the use of the replenishment model—in contrast to its view of approval requirements for rebate models, as discussed below.

Program Abuse by DSH Covered Entities Has Been Particularly Concerning

55. DSH covered entities are responsible for the majority of concerning trends in 340B utilization. The legislative history of the 340B statute reflects that, as of 1992, the statute would apply to a total of 90 DSH covered entities. H.R. Rep. No. 102-384, pt. 2, at 13 (1992). Today, the number of DSH covered entities is nearly 1,200. And, although DSH covered entities account

for less than 10% of all covered entities, their purchases of 340B products at heavily discounted 340B prices in 2022 alone totaled more than $41 *billion*—accounting for nearly 78% of all purchases by covered entities. HRSA, *2022 340B Covered Entity Purchases*, https://bit.ly/3Y1GQ17 (last updated Sept. 2023). That $41 billion in turn represented an increase of 22% from the prior year alone. Adam Fein, *EXCLUSIVE: The 340B Program Reached $54 Billion in 2022—Up 22% vs. 2021*, Drug Channels (Sept. 24, 2023), https://bit.ly/3N21SGl.

56. DSH 340B purchasing grew at an even higher rate in 2023, reaching a total of $51.9 billion, a nearly 25% increase over 2022. HRSA, *2023 340B Covered Entity Purchases*, https://bit.ly/3Yktlsj (last updated Oct. 2024). Overall 340B purchasing reached an astronomical $66.3 billion, 23.4% greater than in 2022. Adam Fein, *The 340B Program Reached $66 Billion in 2023—Up 23% vs. 2022: Analyzing the Numbers and HRSA's Curious Actions*, Drug Channels (Oct. 22, 2024), https://bit.ly/4fhCnwP.

57. Research suggests that this substantial growth may be attributed to DSH covered entities focused on targeting affluent, insured communities, rather than the vulnerable populations the 340B Program was intended to benefit. Reports have shown that certain DSH covered entities systematically acquire, for example, sites of care in wealthy areas with high percentages of commercially-insured patients. *See, e.g.*, Berkeley Rsch. Grp., *340B Covered Entity Acquisitions of Physician-based Oncology Practices* (Apr. 22, 2014) (*Covered Entity Acquisitions*), https://bit.ly/3zqMOz8 (demonstrating that acquisitions by DSH covered entities of oncology practices increased significantly from 2009 to 2012 and involved higher median-income communities compared to the DSH covered entity); Rena M. Conti & Peter B. Bach, *The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities*, 33 Health Affs. 1786 (2014), https://bit.ly/3ZFC9uP (finding an increasing trend of

clinics acquired by DSH covered entities serving communities with lower poverty rates and higher mean and median income levels than that of their DSH parent, particularly among newly-registered DSH covered entities). The expansion by DSH covered entities to wealthier communities runs counter to the 340B Program's original intent of serving low-income patients and advancing health equity.

58. In fact, a 2023 analysis found that 65% of DSH covered entities are not even located in communities HRSA has designated as "medically underserved areas." AIR340B, *340B – A Missed Opportunity To Address Those That Are Medically Underserved: 2023 Update* (2023), https://bit.ly/4eDzyG1 (last visited Nov. 12, 2024).

59. J&J's own evidence demonstrates high levels of Program abuse. Indeed, J&J has identified thousands of transactions in which DSH covered entities received a 340B discount on a unit of drug for which a state Medicaid program also requested a Medicaid rebate, in violation of the prohibition against duplicate discounts. For example, J&J found that, from 2022 to 2024, state Medicaid programs requested Medicaid rebates on:

- Over 500 claims for units purchased at the 340B price by each of St. Joseph's Medical Center and Thomas Jefferson University Hospital;
- Over 300 claims for units purchased at the 340B price by University Medical Center of Southern Nevada;
- Over 200 claims for units purchased at the 340B price by each of University of Michigan Hospital and Health Center, Sister of Charity Hospital, University of Pittsburgh Medical Center – Presbyterian Shadyside and DuBois Regional Medical Center;
- 150 claims for units purchased at the 340B price by Boston Medical Center;
- Over 100 claims for units purchased at the 340B price by each of Mary Hitchcock Memorial Hospital, Norton Hospitals, Inc., and Presence Saint Mary and Elizabeth Medical Center; and

- Over 75 claims for units purchased at the 340B price by each of Ochsner Clinic Foundation and The Mount Sinai Hospital.

Patients Are Not Benefitting From 340B Discounts

60. A growing body of evidence also shows that a substantial proportion of covered entities do not pass on 340B savings to their patients. *See* 2018 GAO Report at 30 (of the 55 covered entities GAO reviewed, only 30 reported passing any portion of their 340B discounts on to patients of contract pharmacies; of those, only "23 indicated that they pass on the full 340B discount to patients, resulting in patients paying the 340B price or less for drugs").

61. Instead, these entities mark up their prices from the 340B discounted level so that they can capture the difference as arbitrage revenue. Dale R. Folwell, N.C. Dep't of State Treasurer, *Overcharged: State Employees, Cancer Drugs, and the 340B Drug Pricing Program* 2 (May 8, 2024), https://bit.ly/3BltgwC (finding that "[w]hen treating state employees with outpatient oncology infusion drugs, North Carolina 340B hospitals levied an average price markup of 5.4 times their discounted acquisition costs"). One recent study found that "[f]rom 2013 to 2021, while the size of the vulnerable population [was] almost halved" due to greater access to insurance, "340B drug discount revenue [for covered entities] grew by 374% . . . ." Martin et al., *Unintended Consequences*, at 2.

62. As early as 2013, Senator Chuck Grassley sounded an alarm that 340B savings discounts were not being passed on to patients, based on information he had received from three North Carolina DSH covered entities. Senator Grassley issued a press release reporting that:

> When I looked at three North Carolina hospitals' use of this program, the numbers showed the hospitals were reaping sizeable 340B discounts on drugs and then upselling them to fully insured patients to maximize their spread. If "nonprofit" hospitals are essentially profiting from the 340B program without passing those savings to their patients, then the 340B program is not functioning as intended.

Press Release, Sen. Chuck Grassley, *Grassley, Cassidy Seek Answers from Georgia Hospital on Discount Drug Program* (Apr. 18, 2023), https://bit.ly/3TJaoOs.

63. Senator Grassley's concern was well founded. Indeed, instead of passing the steep discounts that covered entities (and their contract pharmacies) receive on to vulnerable patients, large pharmacy chains and pharmacy benefit managers are reaping profits from the 340B Program.

64. Various studies have analyzed the resulting financial windfall for PBMs and pharmacies. *See, e.g.*, Peter J. Pitts & Robert Popovian, Food & Drug L. Inst., *340B and the Warped Rhetoric of Healthcare Compassion* (2022), https://bit.ly/3XK1cdG ("Consequently, PBMs are gaining a greater share of overall 340B contract pharmacy business, even as the overall contract pharmacy business shrinks. . . . In 2018 alone, hospitals and pharmacies together made $13 billion in 340B profits. The bulk of the pharmacy take goes to corporations like CVS."); Ted Okon, *Hospitals and for-profit PBMs are diverting billions in 340B savings from patients in need*, STAT (Jul. 7, 2022), https://bit.ly/4dksUn7 (reporting that "one Wall Street analysis estimates that $2.58 billion in 340B savings were siphoned away in 2021 by PBM-controlled pharmacies operated by Walgreens, Caremark, Express Scripts, and OptumRx. That's $2.58 billion in 340B discounts that patients never benefit from.").

65. A New York Times report detailed how one 340B entity that has generated substantial revenue from the Program directed that revenue toward facilities and practices in wealthy neighborhoods, at the expense of facilities that serve vulnerable communities. *See* Katie Thomas & Jessica Silver Greenberg, *How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, N.Y. Times (Sept. 27, 2022), https://bit.ly/3N0Y0p7.

66. With respect to DSH covered entities in particular, studies have shown that many are not using the savings they receive from the 340B Program to fund programs that would benefit

underserved patients. For example, one review found that, for every $10 the 340B hospitals collect in profit, just $1 is invested in charity care. *See* Neal Masia, *Comparing the Financial Health and Charitable Care of 340B and Non-340B Hospitals* 1, 13 (2023), https://bit.ly/3BikgIx.

67. In fact, studies have shown that the majority of DSH covered entities are not providing more care to disadvantaged patients than the average acute-care hospital. One analysis found that 69% of 340B DSH covered entities provide charity care at rates *lower* than the national average. AIR 340B, *Charity Care at 340B Hospitals is on a Downward Trend* 2, 6 (Oct. 2023), https://bit.ly/4eicWep. Similarly, an HHS Office of the Inspector General report found that almost half of the DSH covered entities it surveyed required uninsured patients to pay the full, non-discounted price for their medications at their contract pharmacies, even though the hospitals purchased those drugs at the reduced 340B price. HHS-OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 14 (Feb. 4, 2014), https://bit.ly/3XKxkOf (finding seven of the 15 DSH covered entities surveyed required uninsured patients to pay the full cost of their prescriptions).

J&J Observes Rapidly Increasing 340B Purchasing and Evidence of Potential Program Abuse, and Covered Entities Stymie J&J's Attempts to Audit

68. J&J strongly supports the original intent of the 340B Program and has been a proud participant in the Program for more than three decades. However, J&J has observed concerning trends in the volume of purchases of its drugs at 340B prices. Across its portfolio, purchases of J&J's 340B drugs have increased at a rate three times as fast as its overall sales, and 340B purchases of certain of its products have increased even faster. From the second quarter of 2023 to the second quarter of 2024, for example, 340B purchases of J&J's drug STELARA increased by 55%—about four times as fast as STELARA's overall sales. Likewise, 340B purchases of J&J's drug XARELTO increased by 35%—about seven times as fast as XARELTO's overall sales.

These significant 340B purchase increases have occurred while the population of patients either uninsured or living in poverty has actually declined substantially—from 15.7% of the U.S. population in 2013 to 8.7% in 2021. *See* Martin et al., *Unintended Consequences*, at 8.

69. In April 2024, J&J contacted several covered entities that J&J's data showed had significantly increased their 340B purchasing of J&J products over the past year. J&J attempted to engage in good-faith discussions with these entities so that J&J could better understand the drivers of their substantial increases in utilization and ensure that it did not result in duplicate discounts or diversion. Unfortunately, most entities offered little substantive response.

70. In May and June 2024, J&J submitted letters to HRSA requesting approval to conduct audits of certain entities and explaining J&J's concerns with each entity it sought to audit. Though not required under the 340B statute to do so, J&J's letters explained its "reasonable cause" to believe these entities were not complying with the statutory prohibitions on diversion and duplicate discounting, per 1996 HRSA guidance discussing audit procedures. *See* 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). HRSA's 1996 guidance—though not binding—defines "reasonable cause" to mean that "a reasonable person could believe that a covered entity may have violated a requirement of section 340B(a)(5)(A) or (B) of the PHS Act," *i.e.*, the duplicate discounting and diversion prohibitions. *Id.*

71. J&J's letters to HRSA explained why it had reasonable cause to audit these covered entities. For example, J&J provided information to HRSA demonstrating that purchases by several of the covered entities evidently resulted in duplicate discounts over the past few years—in some cases, hundreds of such examples—in violation of the 340B statute.

72. In addition to describing the need for the audits and the limited response J&J had received from its outreach to these entities, J&J attached an audit work plan to each letter submitted

to HRSA. *See* 61 Fed. Reg. at 65,409 (asking manufacturers to submit work plans for each requested audit). The audit work plans also included data request lists, setting forth the information that J&J's independent audit firm wanted to collect from the covered entities as part of their audit work.

73. HRSA responded to J&J's letters by asking J&J to make certain edits to its work plans, which J&J made. After reviewing J&J's revised plans, HRSA approved audits for several covered entities on June 19, 2024, followed by several more on July 12, 2024, ultimately authorizing J&J to conduct 11 audits of covered entities. J&J's external independent auditor then began notifying the covered entities of the HRSA-approved audits and requested that the covered entities produce the documents and information from the document request list that had been submitted to HRSA as part of the reasonable cause package.

74. Immediately, however, most of the covered entities refused to cooperate with J&J's auditors—in violation of their statutory obligation to participate in HRSA-approved audits, 42 U.S.C. § 256b(a)(5)(C). Eight of the covered entities retained outside counsel, and those entities have refused to provide J&J's auditors with any information. Instead, they have employed a variety of tactics to obstruct J&J from exercising its statutory right to conduct the audits that HRSA has approved.

75. Five covered entities have now filed litigation against HRSA in this district seeking to invalidate its approvals of the audits. *See Or. Health & Sci. Univ. v. Johnson, et al.*, No. 1:24-cv-02184-RC (D.D.C.); *MaineGeneral Med. Ctr. v. Johnson, et al.*, No. 1:24-cv-02187-RC (D.D.C.); *Univ. of Rochester v. Johnson, et al.*, No. 1:24-cv-02268-RC (D.D.C.); *Children's Nat'l Med. Ctr v. Johnson, et al.*, No. 1:24-cv-02563-RC (D.D.C.); *Univ. of Wash. Med. Ctr. v. Becerra, et al.*, No. 1:24-cv-02998-RC (D.D.C.).

76. Other covered entities have cited these actions as grounds for refusing to cooperate with the audits, even though the lawsuits do nothing to alter J&J's statutory right to audit the plaintiff entities, provide no legal basis for halting such audits, and are completely irrelevant to J&J's audits of other covered entities that have not filed suit.

77. To be clear, the 340B statute grants manufacturers an unconditional right to audit a covered entity's records relating to their compliance with the statute's duplicate discounting and diversion prohibitions, subject solely to HRSA processes regarding the number, scope, and duration of the audits for individual covered entities. 42 U.S.C. § 256b(a)(5)(C). Moreover, the 340B statute makes compliance with the audit requirement a condition of a covered entity's eligibility for the 340B Program. *Id.*; *id.* § 256b(a)(4). Therefore, failure to comply with an audit is grounds for termination from the 340B Program. Nonetheless, the substantial majority of J&J's HRSA-approved audits have not proceeded because of unlawful resistance by covered entities.

J&J Makes the Decision to Offer 340B Pricing to Covered Entities Through a Rebate Model

78. To improve transparency in the 340B Program, J&J decided to change the mechanism it uses to offer 340B pricing to DSH covered entities from a discount model to a rebate model. Under J&J's Rebate Model, covered entities would purchase the applicable J&J medicines from wholesalers at commercial prices, similar to the replenishment models used today. Covered entities would then obtain the 340B price through a prompt rebate following the covered entity's submission of commercially standard claims data for each purchase. J&J expects covered entities to receive rebate payments *prior to* the date on which they owe payment to their wholesalers on the initial medicine purchase, under standard payment terms.

79. At implementation, J&J's Rebate Model is intended to have a limited scope. Specifically, J&J will utilize the Rebate Model initially to make the 340B ceiling price available to DSH covered entities on purchases of two J&J drugs—STELARA and XARELTO—for which

recent increases in 340B purchasing have been particularly pronounced. Once a rebate claim is submitted, J&J expects the claim to be validated immediately and paid within approximately seven to ten days. Claim validation simply involves confirming with HRSA's database that the product was purchased by a DSH covered entity registered in the HRSA database, that the product was dispensed or administered by that same registered covered entity, and that the claims data submission occurred within 45 days of the dispense. If a covered entity submits data promptly upon dispensing STELARA or XARELTO, it will obtain 340B rebates *before* payment is due to wholesalers on the underlying purchase under standard payment terms.

80. The Rebate Model offers a number of operational and logistical benefits that will further the integrity of the 340B Program. For example, by providing timely access to data indicating that a covered entity both purchased and dispensed a drug, the Rebate Model substantially increases J&J's ability to identify duplicate discounts on units purchased at the 340B price through other health insurance programs, including Medicaid Fee-for-Service, Medicaid MCOs, commercial PBMs, Medicare Part D, Medicare inflation, and TRICARE retail pharmacy.

81. Additionally, the Rebate Model will enable J&J to comply with the IRA, which requires manufacturers to offer covered entities the lower of the 340B ceiling price or the IRA's MFP for applicable drugs. 42 U.S.C. § 1320f-2(d)(2). Per CMS implementing guidance, manufacturers must offer the reduced price on a unit of a drug within 14 days of receipt of the notification that the unit was dispensed to an MFP-eligible beneficiary. CMS, *Drug Price Negotiation Program: IPAY 2027 Final Guidance* § 40.4 (Oct. 2, 2024), https://bit.ly/3Y719J0. At the most basic level, extending the applicable price point requires a manufacturer to have real-time transparency into whether a MFP-eligible unit was purchased by a covered entity at the 340B ceiling price. The widespread use of replenishment models by covered entities (described above),

however, makes it impossible to identify 340B units in real time because 340B eligibility is only determined when the replenishment order is placed, which occurs well after the initial pharmacy dispense to the 340B patient.

82. Nonetheless, CMS's guidance under the IRA requires manufacturers to report how they are going to determine the MFP with respect to 340B sales at least three months before the MFP requirement goes into effect—and then to certify their compliance with this requirement. CMS, *Drug Price Negotiation Program: IPAY 2027 Final Guidance*, § 90.2.1. To date, CMS has identified no mechanism by which manufacturers can identify 340B claims to comply with this requirement. In fact, CMS recently made clear that it "is not charged with verifying or otherwise reviewing whether a particular drug claim is a 340B-eligible claim and will not, at this time, assume responsibility for deduplicating discounts between the 340B ceiling price and MFP." *Id.* at 55. CMS instead deferred to manufacturers to ensure that they properly pay the lower of the MFP or the 340B price. *Id.* The Rebate Model will solve for this problem.

83. Moreover, the Rebate Model also would provide a mechanism to effectuate the IRA's prohibition against duplication across the MFP and the 340B ceiling price. The IRA specifies that a manufacturer is not required to provide access to the MFP on a drug purchased by a covered entity at the 340B ceiling price if the 340B ceiling price is lower than the MFP. 42 U.S.C. § 1320f-2(d). Without a solution like the Rebate Model that provides clarity into which units were purchased at the 340B ceiling price, J&J will be unable to avail itself of this statutory protection, particularly where regulators refuse to act.

84. Additionally, the Rebate Model will reduce the need for costly, inefficient, and burdensome audits of covered entities—audits that five covered entities have now filed litigation to block. The Rebate Model will also bring transparency to the identification of 340B claims and

thereby substantially improve program integrity, which is sorely needed for the reasons described above.

85. On August 23, 2024, J&J issued a notice to DSH covered entities announcing its intention to adopt the Rebate Model for STELARA and XARELTO. To give the affected DSH covered entities time to become familiar with the Rebate Model, J&J provided a nearly two-month notice period and announced that it planned to implement the Rebate Model on October 15, 2024.

86. In addition, upon implementation of the Rebate Model, J&J plans to offer a significant grace period to further support the transition of DSH covered entities to the Rebate Model. During the grace period, DSH covered entities will be permitted to submit rebate claims outside of the 45-day submission window. In addition, both before and after the implementation date, the administrator of the platform that will be used for the Rebate Model will conduct training programs and will have a customer service team available to address any operational concerns with the platform.

J&J Discusses its Rebate Model with HRSA, which Adopts the Position that the Rebate Model Violates the 340B Statute

87. On July 24, 2024, J&J met with HRSA staff to discuss the trends in 340B utilization that J&J had observed, the resistance to its approved audits from covered entities, and its plans to adopt the Rebate Model. J&J explained that audits were proving to be an inefficient, burdensome, and ineffective means for determining covered entities' compliance with the 340B Program and that the Rebate Model, which provides timely access to data and would better promote program integrity.

88. A week later, counsel for J&J sent a letter to HRSA that provided further detail on the audit issues discussed in the meeting. *See* Letter from Jeffrey L. Handwerker & Paula Ramer to Rear Admiral Krista M. Pedley, Dir., Off. of Special Health Initiatives, HRSA, et al. (July 31,

2024) (attached hereto as Exhibit 1). Counsel for J&J sent follow-up letters to HRSA on August 27 and October 2, updating HRSA on the continued refusal of certain covered entities to participate in the audits HRSA had approved. *See* Letter from Jeffrey L. Handwerker & Paula Ramer to Rear Admiral Krista M. Pedley, Dir., Off. of Special Health Initiatives, HRSA, et al. (Aug. 27, 2024) (attached hereto as Exhibit 2) and Letter from Jeffrey L. Handwerker & Paula Ramer to Rear Admiral Krista M. Pedley, Dir., Off. of Special Health Initiatives, HRSA, et al. (Oct. 2, 2024) (attached hereto as Exhibit 3).

89. J&J also sent a letter to HRSA on July 31, providing a detailed description of its plans to implement the Rebate Model. *See* Letter from Perry E. Knight, Vice President, Law – Strategic Customer Grp., Johnson & Johnson, to Rear Admiral Krista M. Pedley, Dir., Off. of Special Health Initiatives, HRSA, et al. (July 31, 2024) (attached hereto as Exhibit 4). J&J explained that it intended to implement the Rebate Model on October 15, 2024 for DSH purchases of STELARA and XARELTO. *Id.* at 7.

90. On August 14, HRSA responded to J&J's July 31 letter. *See* Letter from Chantelle V. Britton, Dir., Off. of Pharmacy Affs., HRSA, to Perry E. Knight, Vice President, Law – Strategic Customer Grp., Johnson & Johnson (Aug. 14, 2024) ("August 14 Letter") (attached hereto as Exhibit 5). In addition to posing more than two dozen questions to J&J concerning the implementation and operation of the Rebate Model, the August 14 Letter also declared that J&J lacks authority to adopt the model without HRSA's prior approval. *Id.* at 1.

91. HRSA's August 14 Letter noted that the 340B statute directs the HHS Secretary to "'enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, *as provided by the Secretary*) to the manufacturer' shall not exceed the statutory ceiling price formula." *Id.* at 1

(quoting 42 U.S.C. § 256b(a)(1)) (emphasis added by HRSA). The letter continued: "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." *Id.*

92. On August 16, J&J responded in detail to HRSA's August 14 Letter. *See* Letter from Perry Knight, Vice President, Law – Strategic Customer Grp., Johnson & Johnson, to Chantelle V. Britton, Dir., Off. of Pharmacy Affs., HRSA (Aug. 16, 2024) ("August 16 Letter") (attached hereto as Exhibit 6). In addition to answering HRSA's questions, J&J explained that it "interprets [HRSA's] response as a categorical determination that the 340B statute vests [HRSA] with exclusive discretion to determine whether a rebate model is permissible" and reiterated its disagreement with that view and its legal basis for implementation of the model. *Id.* at 1. HRSA has never disagreed with this interpretation.

93. The August 16 Letter also explained that J&J's Rebate Model responds to substantial changes in the operation of the 340B Program and the broader healthcare system over the past three decades. *Id.* The model, J&J wrote, is "designed to address those changes efficiently and in a way that maintains 340B discounts for covered entities while also enabling J&J to manage the impact of the program across other government and commercial programs." *Id.*

94. The August 16 Letter reiterated to HRSA that J&J's Rebate Model would have a limited scope and, as implemented, would apply "only for [DSH] covered entity purchases of STELARA and XARELTO," for which "rebates will typically be paid seven to 10 days" following timely submission of 340B claims. *Id.* at 4. J&J emphasized that, because the model "utilizes data that covered entities already maintain and submit to manufacturers and other stakeholders," "the rebate model can be implemented with minimal disruption and in a manner that largely makes use

of the existing distribution framework." *Id.* J&J further explained that the model also helps to address the potential for duplicate discounts resulting from government programs implemented since the 340B Program's inception, which have layered rebates and other price concessions on top of 340B transactions. *Id.* at 7-8.

95. The August 16 Letter informed HRSA that, as a result of HRSA's August 14 Letter, J&J had delayed the announcement of its Rebate Model from August 15 to August 23, 2024, as a show of good faith. *Id.* at 13. Although J&J was under no obligation to delay its announcement, it did so to give HRSA a chance to review J&J's answers in the August 16 Letter to the more than two dozen questions that HRSA had posed in the August 14 Letter.

96. On August 22, J&J sent HRSA an email with a revised notice detailing the Rebate Model (attached hereto as Exhibit 7). HRSA acknowledged receipt of J&J's email but provided no substantive response. J&J accordingly proceeded to issue an announcement of the Rebate Model to DSH covered entities on August 23.

97. Following J&J's August 23 announcement, several trade associations for large hospital systems issued statements strongly criticizing the Rebate Model and calling for HRSA to take action against J&J. To correct the numerous mischaracterizations of the Rebate Model in these public statements, J&J sent an additional letter to HRSA on September 12, 2024. Letter from Perry Knight, Vice President, Law – Strategic Customer Grp., Johnson & Johnson, to Chantelle V. Britton, Dir., Off. of Pharmacy Affs., HRSA (Sept. 12, 2024) ("September 12 Letter") (attached hereto as Exhibit 8). Among other things, the September 12 Letter reiterated the basis for J&J's legal authority to implement the Rebate Model and explained why the Rebate Model is an important safeguard to advance program integrity, especially in light of the well-documented program abuse described above. *See id.* at 1-4, 8-9. The September 12 Letter also explained to

HRSA why the Rebate Model would not change the universe of eligible 340B claims or the amount of the 340B ceiling price extended to or realized by any covered entity; in other words, all purchases of STELARA and XARELTO that were previously 340B-eligible would remain 340B-eligible. *Id.* at 2-3, 8-9. Finally, the September 12 Letter confirmed that the Rebate Model would not create burdensome administrative requirements for covered entities, because they would be asked simply to submit information they already collect in the normal course of business, including through participation in other drug pricing programs. *Id.* at 3, 9-10.

98. On September 17, after what J&J on information and belief understands was continued petitioning by hospital trade associations, Defendant Johnson sent a letter to J&J. The letter was posted on HRSA's website that same day. Letter from Carole Johnson, Adm'r, HRSA ("September 17 Letter") (attached hereto as Exhibit 9). The September 17 Letter referred to J&J's planned implementation of its Rebate Model and declared: "By way of this correspondence, HRSA provides warning that this unapproved rebate proposal violates J&J's obligations under the 340B statute, and HRSA expects J&J to cease implementation of it." *Id.* at 1.

99. Citing the 340B statute, the September 17 Letter declared that "[t]he Secretary has not 'provided' that the rebates described in J&J's notice should be 'tak[en] into account' in the 'amount required to be paid' for Stelara and Xarelto by disproportionate share hospitals" and concluded that "[i]f J&J implements its rebate proposal without Secretarial approval, it will violate Section 340B(a)(1) of the Public Health Service (PHS) Act." *Id.* at 2. The September 17 Letter also asserted wrongly that "J&J's rebate proposal would require disproportionate share hospitals to purchase Stelara and Xarelto at prices that exceed 'the maximum price[s] that covered entities may permissibly be required to pay' for those drugs." *Id.* The letter stated that "[t]his, too, violates Section 340B(a)(1) of the PHS Act." *Id.*

100. Unlike HRSA's August 14 Letter, its September 17 Letter did not rely solely on the fact that the Secretary had not "provided" for a rebate model. As noted above, in 2010, Congress amended the 340B statute to add language providing that each PPA must "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." 42 U.S.C. § 256b(a)(1). HRSA now asserted—for the first time since that amendment 14 years ago—that the insertion of this language somehow removed rebates as a mechanism for making the 340B price available, even though Congress left the "rebate or discount" language in the same statutory subparagraph entirely untouched. HRSA made no attempt to square this language with its apparently contradictory position that a rebate model would be permissible as long as HRSA gives that model its prior approval. Nor did HRSA attempt to reconcile this position with the continued use of rebate models for ADAPs.

101. Finally, the September 17 Letter admonished that "[b]ecause J&J's rebate proposal, if implemented, violates J&J's obligations under the 340B statute, it subjects J&J to potential consequences," including termination of J&J's PPA and the imposition of CMPs. Exhibit 9 at 2. The September 17 Letter concluded by declaring that "HRSA expects J&J to cease implementation of its rebate proposal immediately and to inform HRSA no later than September 30, 2024, in order to provide adequate notice to covered entities." *Id.* at 3.

102. On September 19, J&J sent HRSA a letter to clarify the misconceptions in the September 17 Letter. Letter from Perry Knight, Vice President, Law – Strategic Customer Grp., Johnson & Johnson, to Carole Johnson, Adm'r, HRSA (Sept. 19, 2024) ("September 19 Letter") (attached hereto as Exhibit 10). Specifically, the September 19 Letter emphasized that: (i) the Rebate Model does not change the universe of eligible 340B claims or the amount of the 340B ceiling price extended to or realized by any covered entity; (ii) the data that covered entities will

be asked to submit is standard data already provided to other program stakeholders, meaning participation in the Rebate Model will not unreasonably burden DSH covered entities, which are sophisticated hospital systems; (iii) covered entities will determine the timing of their rebate payments, because after they submit data showing that they have purchased and dispensed STELARA or XARELTO, that information will be validated immediately, and they will receive rebate payments within seven to ten days; and (iv) the Rebate Model is necessary to ensure program integrity given the significant expansion and well-documented abuse of the program, including through HRSA's own audit findings. *Id.* at 1-5. The September 19 Letter also asked HRSA for a meeting as soon as possible so that J&J and HRSA could continue their discussions. *Id.* at 5.

103. On September 27, 2024, HRSA responded to J&J's September 19 Letter. Letter from Carole Johnson, Adm'r, HRSA ("September 27 Letter") (attached hereto as Exhibit 11). The September 27 Letter warned again that "if J&J proceeds with implementing its rebate proposal without Secretarial approval, it will violate section 340B(a)(1) of the Public Health Service Act." HRSA then admonished that if J&J did not notify HRSA by September 30, 2024 that J&J will cease implementation of the Rebate Model, "HRSA will begin the process outlined in J&J's Pharmaceutical Pricing Agreement related to terminating the agreement," and "will initiate a referral to the HHS Office of Inspector General pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi)," *i.e.*, a CMPs proceeding. *Id.*

104. On September 30, 2024, J&J informed HRSA that it was forgoing implementation of the Rebate Model pending resolution of these issues. Letter from Scott White, Chief Operations Off., N. Am. Innovative Med., Johnson & Johnson, to Carole Johnson, Adm'r, HRSA (Sept. 30, 2024) ("September 30 Letter") (attached hereto as Exhibit 12). The September 30 Letter reiterated

J&J's unwavering commitment to patients and explained that HRSA's position on this issue was detrimental to patients, excessive, and grossly disproportionate. J&J also made clear because of HRSA's unwarranted threats of excessive and unlawful penalties, J&J had no choice but to forgo implementation of the Rebate Model. *Id.* at 2.

105. But for HRSA's erroneous and unlawful letters, J&J would have proceeded with the launch of the Rebate Model on October 15, 2024 as planned. Due to HRSA's actions, however, J&J temporarily paused implementation of the Rebate Model pending confirmation in this litigation that it may proceed without risk of CMPs and without risk that patients would be denied access to life-enhancing and life-saving J&J medicines as a result of termination of J&J's PPA.

106. On October 21, 2024, J&J met with senior HRSA officials to discuss the Rebate Model. In the meeting, J&J reiterated that the proposed Rebate Model: (1) will apply at implementation only to STELARA and XARELTO, J&J's two products subject to the MFP under the first year of the IRA; (2) will apply only to purchases by DSH covered entities; (3) will not reduce the universe of eligible 340B claims, change the 340B price, or diminish the ability of safety net providers to receive the discounts to which they are entitled; (4) will validate 340B claims based only on whether units were purchased by a DSH covered entity and dispensed or administered by such an entity; and (5) will provide payment of rebates within seven to ten days of receipt of the relevant claims data. J&J also made clear that it will use the data it receives from the Rebate Model to identify and mitigate the risk of subsequent duplicate discounts from occurring in other drug purchase channels—*not* 340B.

107. Following the meeting, while maintaining its legal position that HRSA's approval of its Rebate Model was not required, J&J sent an email to HRSA inquiring whether HRSA would approve J&J's implementation of the Rebate Model as proposed if HRSA approval were required.

Email from Jeffrey Handwerker to Rear Admiral Krista Pedley, Dir., Off. of Special Health Initiatives, HRSA, at 2 (Oct. 21, 2024) (attached hereto as Exhibit 13). Noting that time is of the essence, J&J requested that HRSA provide a response by October 28, 2024. *Id.*

108. HRSA did not provide a response by the requested date. The following day, October 29, J&J sent an email to HRSA communicating that, in light of the lack of response, J&J understood that HRSA's position remained unchanged from its prior letters to J&J, and J&J would proceed consistent with that understanding. *See id.* at 1-2.

109. On October 30, 2024, HRSA responded that HRSA was "still reviewing the information [J&J] submitted." *See id.* at 1.

110. HRSA did not contact J&J again, despite having more than two weeks beyond the date that J&J initially requested a response. Earlier today, J&J sent HRSA an email stating that: (1) J&J understands the August 14, September 17 and September 27 letters to reflect HRSA's final determination on whether HRSA has the authority to preapprove rebate models and whether J&J's proposed Rebate Model is consistent with the 340B statute; and (2) J&J would be filing suit today challenging HRSA's final determinations, as set out in the August 14, September 17 and September 27 letters, that J&J may not proceed with its Rebate Model without HRSA's approval and that J&J's Rebate Model is not permissible under the 340B statute. Email from Jeffrey Handwerker to Rear Admiral Krista Pedley, Dir., Off. of Special Health Initiatives, HRSA (Nov. 12, 2024) (attached hereto as Exhibit 14).

LEGAL ALLEGATIONS

111. The 340B statute requires the HHS Secretary to "enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (*taking into*

account any rebate or discount, as provided by the Secretary)" by covered entities is at or below the 340B ceiling price. 42 U.S.C. § 256b(a)(1) (emphasis added).

112. From the start, all stakeholders, including Congress and HRSA, understood that language to permit either rebates or discounts as the mechanism for providing reduced prices to covered entities. *See* 62 Fed. Reg. at 45,824 ("[S]ection 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.'") (quoting H.R. Rep. No. 102-384, pt. 2, at 16). As a result, manufacturers are free to select a pricing mechanism at their discretion: Where the 340B statute does not "prohibit[]" manufacturers "from adopting their policies" imposing reasonable conditions on 340B purchases, such policies "are lawful" and do not require agency approval. *Sanofi Aventis*, 58 F.4th at 703-04; *Novartis Pharms. Corp.*, 102 F.4th at 460-61 (holding that the 340B statute "preserves" manufacturers' ability to impose reasonable conditions, including "request[ing] standard information" from covered entities).

113. Contrary to HRSA's current position, the parenthetical phrase "(taking into account any rebate or discount, as provided by the Secretary)" does not mean that manufacturers must obtain advance approval from HRSA before adopting a rebate model. The parenthetical phrase in question appears in subsection (a) of 42 U.S.C. § 256b, which is titled "Requirements for Agreement with Secretary." The words immediately before and immediately after that parenthetical phrase refer to the terms of the agreements known as PPAs. Specifically, the statute provides that "The Secretary shall enter into an *agreement with each manufacturer of covered outpatient drugs under which* the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed" the 340B ceiling price. *Id.*

114. Thus, to the extent the agency has authority to direct a pricing mechanism at all, it must do so through the PPA. But HRSA never placed such logistical terms in the PPA. Where, as here, the PPA is silent as to the mechanism by which the 340B price shall be offered, a manufacturer is free to choose its pricing mechanism without HRSA approval. *See Sanofi*, 58 F.4th at 704 (explaining the statute "imposes only a price term for drug sales to covered entities, leaving all other terms blank"). Manufacturers accordingly retain discretion to select a pricing mechanism.

115. In its September 17 Letter, HRSA asserted that the "must-offer" provision of the 340B statute, which Congress added in 2010, prohibits manufacturers from adopting a pricing mechanism in which covered entities purchase 340B drugs at commercial prices and then receive a rebate to effectuate the statutory ceiling price. Exhibit 9 at 1-2. On HRSA's telling, a manufacturer who relies on rebates to effectuate 340B discounts necessarily fails to "offer" the 340B ceiling price. But HRSA has never before argued that adoption of the must-offer requirement altered the pricing mechanisms available to manufacturers. Any such argument would be untenable, given that the statutory language referencing rebates as an available pricing mechanism remained unchanged by the 2010 amendment. Moreover, HRSA's newfound interpretation of the must-offer provision would preclude the use of any rebate model *at all*—with or without HRSA's permission—and render superfluous the statute's reference to "any *rebate* or discount." 42 U.S.C. § 256b(a)(1) (emphasis added).

116. The September 17 Letter's reading of the must-offer provision is also inconsistent with how the language has been interpreted in decisions of the D.C. Circuit and Third Circuit, which confirm that the must-offer provision of the 340B statute allows manufacturers to impose "reasonable conditions" with respect to the offering of 340B drugs. *Novartis*, 102 F.4th at 459-

61; *Sanofi*, 58 F.4th at 704-05. HRSA's interpretation additionally conflicts with its prior insistence that it can render use of rebates lawful through "Secretarial approval." Exhibit 9 at 2.

117. Interpreting the must-offer provision to require upfront discounts also fails as a matter of ordinary meaning. The statute provides that the PPA "shall require that the manufacturer offer each covered entity covered outpatient drugs for *purchase* at or below the applicable ceiling *price*." 42 U.S.C. §256b(a)(1) (emphases added). "Price" means "[t]he cost of acquiring or producing something." *Price*, Black's Law Dictionary (12th ed. 2024). Under the plain language of the statute, the "price" at which covered entities will be able to "purchase" J&J drugs under its Rebate Model is the ceiling price.

118. Indeed, it is commonly understood that "[t]he transaction price of a prescription drug . . . includes discounts and rebates." *PhRMA v. David*, 510 F. Supp. 3d 891, 898 (E.D. Cal. 2021). Manufacturers routinely "*offer*[] lower *prices* . . . through *rebates* or discounts." *Cash & Henderson Drugs, Inc. v. Johnson & Johnson*, 799 F.3d 202, 206 (2d Cir. 2015) (emphasis added); *see also, e.g., FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (explaining that drug manufacturers may offer "cash rebates" to wholesalers that result in a wholesaler "acquir[ing] the drugs for *prices* less than the listed WAC") (emphasis added). Stated simply, an offer to purchase a drug and then receive a rebate is an offer to purchase the drug at the price after the rebate. J&J's Rebate Model therefore does not result in covered entities paying more than the ceiling price.

119. That understanding aligns with HHS's implementation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b). Under AKS safe-harbor regulations, a "discount" is "a reduction in the amount a buyer … is charged for an item or service based on an arms-length transaction." 42 C.F.R. § 1001.952(h)(5). A rebate, in turn, is "any *discount* the terms of which

are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale." *Id.* § 1001.952(h)(4). In other words, a "rebate" is a type of "reduction in the amount a buyer … is charged for an item." The purchaser is still "charged" the reduced amount, regardless of whether the reduction is pre- or post-offer. *See also, e.g.*, 42 U.S.C. § 1396r-8(c)(2)(C)(ii)(I) ("best price" under Medicaid Drug Rebate Program "shall be inclusive of cash discounts, … volume discounts, and rebates"); 42 C.F.R. § 447.505(b) (implementing Medicare regulation defining "[b]est price" to include "applicable discounts, rebates, or other transactions that adjust prices either directly or indirectly"); 42 U.S.C. § 1395w-102(d)(1)(B) (Medicare Part D statute providing that "negotiated prices … shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered [Medicare] Part D drugs"); 42 C.F.R. § 423.100 (defining "[p]rice concession" for Medicare Part D as "any form of discount, direct or indirect subsidy, or rebate received by the Part D [plan] sponsor . . . that serves to decrease the costs incurred under the Part D plan").

120. For these reasons, the "must-offer" provision by its plain terms is satisfied when a covered entity is initially charged a higher price and subsequently receives a rebate that reduces the net price to the ceiling price for that drug. And as discussed above, here, if DSH covered entities submit the required information in a timely fashion, they will obtain the 340B rebate *before* payment is due to wholesalers on the underlying purchase.

121. Nor does any other provision of the 340B statute limit manufacturers' discretion to select a pricing mechanism or grant HRSA discretion to mandate one through the August 14, September 17, and September 27 letters. HRSA lacks "broad rulemaking authority" under the 340B statute and is authorized to issue binding regulations only in certain narrow areas specified

by Congress. *PhRMA v. HHS*, 43 F. Supp. 3d 28, 42 (D.D.C. 2014); *see PhRMA v. HHS*, 138 F. Supp. 3d 31, 48 (D.D.C. 2015).

122. HRSA's position that J&J may not implement the Rebate Model without HRSA consent, as articulated in the August 14, September 17, and September 27 letters, is thus inconsistent with the 340B statute and governing law.

123. Moreover, HRSA's refusal to approve J&J's Rebate Model under the circumstances is arbitrary and capricious. In rejecting the Rebate Model, HRSA failed to adequately consider that the replenishment models that the majority of covered entities use, which HRSA has acquiesced in for more than a decade, operate just as rebate models do. Under a replenishment model, drug units are purchased at WAC, and the 340B price is realized once the covered entity's third-party administrator determines that a sufficient number of units have been dispensed to 340B-eligible patients and places an order to replenish the stock of the drug. The Rebate Model is similar in critical respects—drug units are purchased at WAC and the 340B price is realized after the initial sale, albeit much faster than the weeks or months a replenishment model can sometimes require. And, unlike replenishment models, manufacturer rebate models are expressly contemplated and authorized by the 340B statute.

124. Nowhere in HRSA's communications with J&J did the agency adequately explain why it treated J&J's Rebate Model differently from the replenishment models that covered entities have used for over a decade. Instead, in its September 17 letter, HRSA tried to distinguish replenishment models from rebate models by asserting that, under the "typical replenishment structure," the covered entity purchases the initial unit at WAC and then subsequent units are replenished at the 340B price. Exhibit 9 at 2. But that is materially the same as how J&J's Rebate Model will work. The covered entity will purchase a unit at WAC and then obtain a rebate within

seven to ten days after submitting data supporting the 340B purchase. The rebate plays the same role as the replenishment unit in ensuring that the prior purchase nets the 340B price.

125. Moreover, HRSA's assertion in the September 17 letter that replenishment models are distinct from rebate models because "covered entities voluntarily choose to use replenishment processes" whereas "J&J's proposal is not voluntary for covered entities" is quintessentially arbitrary. Exhibit 9 at 2. It treats one class of program stakeholders—covered entities—more favorably than another set of stakeholders—manufacturers. If covered entities are permitted under the statute voluntarily to implement replenishment models without HRSA consent, then it surely follows that manufacturers could voluntarily implement rebate models without HRSA consent. This is especially so given that the statute expressly references rebates as a means of effectuating 340B prices but nowhere mentions replenishment models.

126. HRSA's letters threaten J&J with substantial legal exposure—including to CMPs and the termination of its PPA (leading to loss of access to all J&J drugs for Medicare Part B and Medicaid recipients nationwide)—for implementing its Rebate Model. As a result, the letters are final agency actions and ripe for judicial review. *See Bellion Spirits, LLC v. United States*, 7 F.4th 1201, 1209 (D.C. Cir. 2021); *see also Ipsen Biopharms., Inc. v. Azar*, 943 F.3d 953, 957 (D.C. Cir. 2019) (similar); *Sackett v. EPA*, 566 U.S. 120, 126-27 (2012).

127. *First*, because they declare HRSA's binding, final interpretation of the 340B statute—that manufacturers may not implement rebate models unilaterally, and that HRSA may direct a pricing mechanism by letter and impose severe penalties for non-compliance—the August 14, September 17, and September 27 Letters "mark[] the consummation of [HRSA's] decisionmaking process and [are] not of a merely tentative or interlocutory nature." *Bellion Spirits*, 7 F.4th at 1208 (quoting *Soundboard Ass'n v. FTC*, 888 F.3d 1261, 1267 (D.C. Cir. 2018)).

Plainly, "[t]he letter[s] put[] forth the agency's official position about how the [340B statute] appl[ies] to" J&J's plan to implement its Rebate Model. *Id.* The September 27 Letter is unequivocal: HRSA has declared that J&J's Rebate Model is unlawful and that it will refer J&J for CMPs and begin the process to terminate its PPA if J&J proceeds as planned. HRSA has not revisited that determination in any subsequent communication with J&J. The agency's decision-making process is unquestionably consummated.

128. *Second*, the letters are "action[] by which rights or obligations have been determined, or from which legal consequences will flow." *Id.* (quoting *Soundboard Ass'n*, 888 F.3d at 1267). HRSA expects immediate compliance, and it will undoubtedly argue in any CMP proceeding that the September 17 Letter and September 27 Letter "extinguish[ed] any willfulness defense [J&J] otherwise might assert" about the legality of its Rebate Model, which, if successful, would expose J&J to penalties. *Id.* at 1209. In light of those purported legal consequences, the September 17 and September 27 letters are final. *See id.*; *cf. AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 57-58 (D. Del. 2021) (concluding an HHS 340B advisory opinion was final agency action).

129. HRSA's letters are also ripe for review. J&J's challenge is "fit for judicial decision" because it involves final agency action "and because 'judicial intervention' would not 'inappropriately interfere with further administrative action.'" *Bellion Spirits*, 7 F.4th at 1209 (quoting *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 733 (1998)). As for "hardship to the parties," if the Court were to withhold review, J&J "could obtain judicial review of [HRSA's] position only by flouting the [August 14 Letter, September 17 Letter, and September 27 Letter] and [implementing the Rebate Model], thereby risking the imposition of civil [monetary] penalties" and termination of its PPA. *Id.* "The ripeness requirement does not require parties to

subject themselves to that kind of jeopardy." *Id.* (citing *Unity08 v. FEC*, 596 F.3d 861, 866 (D.C. Cir. 2010)).

CLAIM FOR RELIEF

Violation of the Administrative Procedure Act (Declaratory/Injunctive Relief – HRSA's August 14 Letter, September 17 Letter, and September 27 Letter are arbitrary, capricious, an abuse of discretion, and not in accordance with law)

130. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

131. The APA requires courts to "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), or is "in excess of statutory jurisdiction, authority, or limitations," *id.* § 706(2)(C).

132. The 340B statute expressly contemplates rebates as a mechanism through which a manufacturer may provide 340B pricing to covered entities, but the statute does not require a specific mechanism. To the extent the statute vests Defendants with any authority to direct a pricing mechanism, they may do so only through the PPA. Because the PPA does not specify a pricing mechanism, the 340B statute authorizes manufacturers to select a rebate model.

133. HRSA's August 14 Letter, September 17 Letter, and September 27 Letter therefore improperly declare that J&J may not implement its Rebate Model without prior HRSA approval.

134. HRSA's declaration, as set out in its August 14, September 17, and September 27 letters, that J&J's Rebate Model violates the 340B statute is final agency action that is arbitrary, capricious and not in accordance with law, 5 U.S.C. § 706(2)(A), and in excess of statutory jurisdiction or authority, *id.* § 706(2)(C).

135. HRSA's declaration, as set out in its August 14, September 17, and September 27 letters, that J&J may not implement its Rebate Model without HRSA approval is also final agency

action that is arbitrary, capricious, and not in accordance with law, *id.* § 706(2)(A), and in excess of statutory jurisdiction or authority, *id.* § 706(2)(C).

136. The August 14 Letter, September 17 Letter, and September 27 Letter must therefore be set aside and vacated.

PRAYER FOR RELIEF

NOW, THEREFORE, Plaintiff Johnson & Johnson Health Care Systems Inc. requests a judgment in its favor against Defendants as follows:

1. Declare that HRSA's determination, as set out in HRSA's August 14 Letter, September 17 Letter, and September 27 Letter, that J&J may not implement a rebate model without HRSA's consent is arbitrary and capricious, an abuse of discretion, and unlawful under the APA and the 340B statute;

2. Set aside and vacate HRSA's August 14 Letter, September 17 Letter, and September 27 Letter and declare that J&J's Rebate Model is lawful under the 340B statute;

3. Enjoin Defendants from commencing any enforcement action against J&J relating to or arising from J&J's implementation of the Rebate Model;

4. Award Plaintiff reasonable attorneys' fees and costs; and

5. Grant such other and further relief as the Court may deem appropriate.

Dated: November 12, 2024

Respectfully submitted,

/s/ Jeffrey L. Handwerker

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CERTIFICATE OF SERVICE

I hereby certify that this document will be served on Defendants in accordance with Fed. R. Civ. P. 4.

/s/ Jeffrey L. Handwerker

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