IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRISTOL MYERS SQUIBB COMPANY, Route 206 & Province Line Road, Princeton, New Jersey 08543, *Plaintiff*, v. CAROLE JOHNSON, in her official capacity as ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION, 5600 Fishers Lane, Rockville, Maryland 20852, and XAVIER BECERRA, in his official capacity as SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue, S.W., Washington, D.C. 20201, *Defendants*.	)	Civil Action No. 1:24-cv-03337

COMPLAINT

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

PRELIMINARY STATEMENT

1. When Congress enacts a statute authorizing multiple means to achieve the same end, one pathway is every bit as lawful as another. BMS brings this case because HRSA, the sub-agency of HHS responsible for overseeing the 340B Drug Pricing Program, has denied that fundamental truism.

2. The statute governing the 340B Program contemplates that participating drug manufacturers will offer to sell their products at steeply reduced amounts under specified conditions. The parties on the other end of the transaction—known as "covered entities"—reap the benefits of below-market pricing on each 340B-eligible unit. The 340B Program thereby confers a significant financial benefit on covered entities. But Congress knew that the 340B Program's significant financial benefits could lead to abuse. So Congress built safeguards into the statute, prohibiting covered entities from seeking the 340B price on a prescription that also will be subject to a Medicaid Drug Rebate Program (MDRP) rebate, forbidding diversion of 340B-priced units to ineligible individuals, and permitting manufacturers to audit covered entities' compliance.

3. A participating manufacturer like BMS may choose how to implement 340B pricing on a 340B-eligible unit. The 340B statute spells out two options. Under the first, after the drug has been purchased at the commercial price and dispensed, the manufacturer can honor the 340B price by remitting a "rebate" to the covered entity equal to the difference between the commercial price and the 340B price. 42 U.S.C. § 256b(a)(1). Under the second, the manufacturer can charge the 340B price initially, reflecting an upfront "discount." *Id.*

4. BMS, a participant in the 340B Program since its inception decades ago, has historically used a discount model to effectuate 340B pricing. Over time, however, BMS has seen the 340B Program become rife with abuse. As multiple government agencies' audits (including

HHS's own) have revealed, covered entities have systematically violated the 340B statute—propelled by commercial pharmacies, third-party administrators, and other middlemen seeking to profit from covered entities' ability to "buy low," at the 340B price, and "sell high," through reimbursement at commercial rates, yielding a profit "spread." Manufacturers' use of a discount model has unintentionally enabled these excesses, making it impossible to ensure program integrity, including compliance with the 340B statute's prohibitions against MDRP-340B duplication and drug diversion.

5. After years of abuse and without any meaningful HHS enforcement to solve these worsening concerns, BMS informed HHS on October 22, 2024, that it intends to shift away from a discount model and toward a rebate model. BMS's intended rebate model is authorized by the 340B statute and accords with HHS practice endorsing the AIDS Drug Assistance Program (ADAP) rebate model as well as the "replenishment" model overwhelmingly used by covered entities.

6. Even though rebate and discount models stand on equal statutory footing, HHS has determined that BMS's intended rebate model would be inconsistent with the 340B statute and requires HHS's pre-approval prior to implementation. That determination is unlawful three times over.

7. *First*, HHS cannot wall off one of the 340B statute's available means of providing 340B pricing on eligible units. Congress gave manufacturers options, and the agency cannot read one out of the statute without violating the Administrative Procedure Act (APA).

8. *Second*, HHS's determination is arbitrary and capricious: The agency cannot lawfully turn a statutory choice into a regulatory command, force BMS to offer 340B pricing where none is owed, treat similarly situated rebate models differently without a reasoned basis for doing

so, or task BMS with preventing MFP-340B duplication and then block its lawful attempt to do just that.

9. *Finally*, HHS's decision is illogical and runs afoul of substantive due process principles that guard against irrational governmental action.

10. For each of these reasons, HHS's action is unlawful and must be set aside.

PARTIES

11. Plaintiff Bristol Myers Squibb Company is a global biopharma company that is pursuing bold science to define what's possible for the future of medicine and the patients it serves. Its mission is to discover, develop, and deliver innovative medicines that help patients prevail over serious diseases. BMS is incorporated in Delaware and has its principal place of business at Route 206 & Province Line Road, Princeton, New Jersey 08543.

12. Defendant Carole Johnson is the Administrator of HRSA, an operating component within HHS. Defendant Johnson maintains an office at 5600 Fishers Lane, Rockville, Maryland 20852, and is sued in her official capacity only.

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

JURISDICTION AND VENUE

14. This Court has jurisdiction to hear this matter under 28 U.S.C. § 1331, as this civil action arises under the laws of the United States; 28 U.S.C. § 1346, as this case involves claims against the federal government; 28 U.S.C. § 1361, as this is an action to compel officers of the United States to perform their duty; and 28 U.S.C. §§ 2201–2202, as there is an actual justiciable

controversy for which Plaintiff seeks a declaration of its rights by this Court, as well as injunctive relief to prevent Defendants from violating the law.

15. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (e) because this civil action involves Defendants who are officers of the United States acting in their official capacities and one of the Defendants maintains his office and conducts business in this judicial district.

FACTUAL BACKGROUND

The 340B Program

16. In 1992, Congress established the 340B Drug Pricing Program, mandating that, under specified circumstances, participating pharmaceutical manufacturers offer each of their covered outpatient drugs to qualifying hospitals and clinics that primarily serve certain vulnerable patient populations—known as covered entities—at or below a significantly reduced price determined by a specified statutory formula—known as the 340B ceiling price. Under the statute, a manufacturer "shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a).

17. Courts have confirmed that, to satisfy the "must offer" requirement, the offer need only be "bona fide"; reasonable conditions, including those concerning data reporting, may apply. *See, e.g.*, *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 461 (D.C. Cir. 2024) (embracing HHS's decades-long policy in favor of manufacturers' "reasonable conditions"); *see also Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696, 701, 706 (3d Cir. 2023) (affirming manufacturer requirement that covered entities provide claims data).

18. For federal reimbursement to be available under Medicaid and Medicare Part B for manufacturers' covered outpatient drugs, manufacturers must enter into an agreement—known as

the Pharmaceutical Pricing Agreement (PPA)—and thereby participate in the 340B Program. 42 U.S.C. § 1396r-8(a)(1).

Statutory Background

19. Once a manufacturer agrees to participate in the 340B Program, the statute calls out two ways in which a manufacturer can implement 340B pricing for a 340B-eligible unit. The first option is to give a rebate. The second is to provide a discount. Congress built that choice into the statutory text when it mandated 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 . . . does not exceed" the statutorily defined 340B ceiling price. 42 U.S.C. § 256b(a)(1) (emphasis added).

20. This rebate-or-discount choice is reflected throughout the 340B statute. The statute prohibits subjecting the same unit to both an MDRP rebate and 340B pricing—a phenomenon known as MDRP-340B duplication—and "prohibit[s] duplicate discounts *or* rebates." 42 U.S.C. § 256b(a)(5) (emphasis added).

21. By its plain terms, the 340B statute limits the availability of 340B pricing. For example, the 340B statute requires a manufacturer to offer 340B pricing to only a "covered entity" and defines a "covered entity" as an entity that, among other things, is in compliance with both the statutory prohibition against MDRP-340B duplication and the statutory prohibition against a covered entity furnishing a 340B-priced unit to an individual who is not a patient of the covered entity, known as 340B diversion. 42 U.S.C. § 256b(a)(1) (requiring a manufacturer to offer 340B pricing only to a "covered entity"), *id.* § 256b(a)(4) (defining "covered entity" as an entity that, among other things, is in compliance with paragraph (5)), *id.* § 256b(a)(5) (prohibiting MDRP-340B duplication and 340B diversion). Accordingly, where a unit of a drug is either subject to an

MDRP rebate or furnished by a covered entity to a non-patient, there is no obligation for the manufacturer to offer 340B pricing.

22. In addition, there is no obligation to offer 340B pricing multiple times on the same unit—referred to here as 340B replication—which occurs when multiple covered entities claim 340B pricing on the same unit. 42 U.S.C. § 256b(a)(1).

The 340B Program Is Rife with Programmatic Noncompliance by Covered Entities

23. Covered entities systemically operate outside of the 340B Program's statutory limits, as repeatedly confirmed by multiple government agencies.

24. For example, HHS's own audits consistently find widespread violations of the prohibition on MDRP-340B duplication as well as the prohibition on 340B diversion. HRSA, Audit Results of Covered Entities (https://www.hrsa.gov/opa/program-integrity); Gov't Accountability Off. (GAO), *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, GAO-21-107 at 14 (Dec. 2020) (https://www.gao.gov/assets/gao-21-107.pdf) (from 2012 to 2019, HHS audits of covered entities found 1,536 instances of program noncompliance, 429 of which concerned Medicaid-340B duplication, 546 of which concerned 340B diversion, and 561 of which concerned other covered entity eligibility requirements).

25. In addition, a January 2020 GAO report found that "HHS does not have reasonable assurance that states and covered entities are complying with the prohibition on [MDRP-340B] duplicate discounts." GAO, 340B Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, GAO-20-212, (Jan. 2020) (https://www.gao.gov/assets/gao-20-212.pdf) (GAO Highlights). The report concluded that "[l]imitations in federal oversight impede [HHS's] ability to ensure compliance with the prohibition on [MDRP-340B] duplicate discounts" and that HHS's failure to ensure that covered

entities are complying with 340B program requirements "not only puts drug manufacturers at risk of providing [MDRP-340B] duplicate discounts, but also compromises the integrity of the 340B Program." *Id.* at 27.

26. In reaching this conclusion, GAO observed that "the potential for [MDRP-340B] duplicate discounts has increased due to substantial growth in the 340B Program and the expansion of" the MDRP. *Id*. at 2.

27. GAO further observed that "the HHS Office of Inspector General [(OIG)] and others have identified challenges covered entities and states face in identifying 340B drugs provided to Medicaid beneficiaries, and thus in preventing duplicate discounts." *Id.* at 3 (citing HHS OIG, State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates, OEI-05-14-00430 (June 2016) (https://oig.hhs.gov/documents/evaluation/2918/OEI-05-14-00430-Complete%20Report.pdf); National Ass'n of Medicaid Dirs., Medicaid and the 340B Program: Alignment and Modernization Opportunities (May 2015) (https://medicaiddirectors.org/wp-content/uploads/2022/02/NAMD-White-Paper-on-Medicaid-and-340B-Alignment_pdf.pdf); Medicaid & CHIP Payment & Access Comm'n, The 340B Drug Pricing Program and Medicaid Drug Rebate Program: How They Interact (May 2018) (https://www.macpac.gov/wp-content/uploads/2018/05/340B-Drug-Pricing-Program-and-Medicaid-Drug-Rebate-Program-How-They-Interact.pdf)). GAO itself had previously "identified weaknesses in HRSA's oversight that impede its ability to ensure compliance with 340B Program requirements, including the prohibition on duplicate discounts." GAO, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480 (June 2018) (2018 GAO Report) (https://www.gao.gov/assets/d18480.pdf)).

28. Among other things, GAO "identified several areas of weakness in HRSA's oversight processes that impede its ability to ensure that duplicate discounts are prevented or remedied." *Id*. at 23.

29. For example, "HRSA does not assess whether covered entities are actually following state policies and procedures regarding the use and identification of 340B drugs for Medicaid beneficiaries." *Id.* at 24. "Without fully assessing compliance with state policy, HRSA's audits do not provide the agency with reasonable assurance that covered entities are taking the necessary steps to prevent duplicate discounts. As a result, drug manufacturers are at risk of being required to erroneously provide duplicate discounts for Medicaid drugs." *Id.* at 24–25.

30. In addition, "HRSA audits do not assess for the potential for duplicate discounts in Medicaid managed care." *Id.* at 25. And "the agency does not require covered entities to take the same actions to address duplicate discounts for managed care claims that HRSA learns about through its audits or other means." *Id.* at 26. "This is particularly problematic as the majority of Medicaid enrollees, prescriptions, and spending for drugs are in managed care, and the drug manufacturers we contacted believe that duplicate discounts are more prevalent in Medicaid managed care than" Medicaid fee for service. *Id*.

31. These reports are merely illustrative of the raft of similar governmental findings over time. *See, e.g.*, House Energy & Commerce Comm., Review of the 340B Drug Pricing Program at 36–38 (Jan. 10, 2018) (https://tinyurl.com/58rpjkfv). For example, an HHS audit revealed that a "covered entity and its off-site outpatient facilities did not accurately appear" on HHS's 340B Medicaid Exclusion File, which HHS designed "to prevent duplicate discounts by notifying states and manufacturers which drug claims are not eligible for Medicaid rebates." *Id.* at 36 & 37 n.182. A 2023 GAO report documented covered entities' self-reported noncompliance

with the 340B Program's prohibitions on duplicate discounts and diversion. GAO, *340B Drug Discount Program: Information About Hospitals That Received an Eligibility Exception as a Result of COVID-19*, GAO-23-106095 (May 11, 2023) (https://www.gao.gov/assets/gao-23-106095.pdf). These self-disclosed violations represent a small fraction of the full range of abuses, as "HRSA does not know if covered entities have effectively identified the full extent of noncompliance." *Id.* at 20 n.32.

32. Racked with abuse, the 340B Program has grown at a rapid clip and strayed from its mission to support the care of uninsured, low-income patients. IQVIA, *Unintended Consequences: How the Affordable Care Act Helped Grow the 340B Program* (Aug. 30, 2024) (https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2024/unintended-consequences-how-the-affordable-care-act-helped-grow-the-340b-program.pdf). Due in part to the Affordable Care Act's expansion of the Medicaid program, that vulnerable patient population was cut in half between 2013 and 2021, even as 340B revenue swelled by 374% during the same period. *Id.* at 2, 8.

33. Left unchecked, these abuses will continue to fuel the runaway growth of the 340B Program. Purchases under the 340B Program reached a record $66.3 billion in 2023, representing a 23% year-over-year growth compared to the total purchase volume in 2022. *See* Adam J. Fein, *The 340B Program Reached $66 Billion in 2023—Up 23% vs. 2022: Analyzing the Numbers and HRSA's Curious Actions* (Oct. 22, 2024) (https://www.drugchannels.net/2024/10/the-340b-program-reached-66-billion-in.html).

HHS Has Long Permitted 340B Rebate Models, Without Preapproval

AIDS Drug Assistance Program Rebate Model

34. HHS formally permitted a cash-rebate model over 25 years ago, and it did so without requiring agency pre-approval from the manufacturers involved.

35. In 1997, HHS initiated a notice-and-comment process to formally "recognize" a cash-rebate model that was already in place between certain manufacturers and ADAPs, a type of covered entity. The notice proposed recognizing cash rebates to ADAPs as a means of making the 340B price available, so long as the rebate amount resulted in a price at or below the 340B ceiling price. 62 Fed. Reg. 45,823, 45,824 (Aug. 29, 1997).

36. The next year, HHS published a final notice that "recognize[d] rebates obtained by the State ADAPs or their components that equal or exceed the 340B discount provided by the statutory ceiling price as a method of participating in the 340B program." 63 Fed. Reg. 35,239, 35,239 (June 29, 1998). HHS thereby expressly recognized—without agency pre-approval—a cash-rebate model that had been chosen and implemented by manufacturers. *See id.* at 35,240 (rebate agreements that predated the notice were not required to be renegotiated if they met the notice's requirements). Moreover, HHS recognized that a rebate model necessitated submission of claim data in support of rebate claims, consistent with ordinary business practices. *See id.* at 35,239, 35,240, 35,241, 35,242.

Product Replenishment Model

37. HHS has long informally permitted covered entities to use an *in-kind* or *product* rebate model, with much wider-ranging impact than the ADAP rebate model. *See, e.g.*, HRSA, 340B Peer-to-Peer Program: 340B Compliance Improvement Guide at 36–37 (Oct. 1, 2015) (https://www.hrsa.gov/sites/default/files/hrsa/opa/compliance-improvement-guide.pdf). This so-

called product replenishment model is now the default approach by which covered entities access the 340B price. It has never been the subject of any formal pre-approval process.

38. At the 340B Program's outset, covered entities generally used a *physical* inventory model. This model physically segregated units purchased at the 340B price from units purchased at the commercial price and required covered entities to determine whether a prescription was 340B-eligible—that is, the unit met the criteria to be purchased at the 340B price—*before* it was dispensed. *See* 340B Health, *Key Terms* (https://www.340bhealth.org/members/340b-program/key-terms/); HHS OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 at 5 (Feb. 4, 2014) (https://oig.hhs.gov/documents/evaluation/2914/OEI-05-13-00431-Complete Report.pdf).

39. If the prescription was 340B-eligible, the covered entity dispensed a 340B-priced unit; if not, the covered entity dispensed a commercially purchased unit. *See id.* In this way, both covered entities and manufacturers alike could have some confidence that a 340B-priced unit would be dispensed only where a prescription was 340B-eligible.

40. Over time, covered entities shifted from the physical inventory model to a *virtual* inventory model—the product replenishment model—where the covered entity no longer maintains distinct 340B-priced and commercially priced inventories and no longer determines 340B eligibility at the time of dispensing. Under the product replenishment model, units purchased at the 340B price are commingled in a single inventory with units purchased at the commercial price, and a prescription's 340B eligibility is determined after the fact—two conveniences for the covered entity that have fueled the 340B Program's unchecked growth and increased risk of diversion and other non-compliance.

41. The product replenishment model operates in four steps. *First*, a covered entity purchases a unit at the commercial price, places it in a single, common inventory, and dispenses it without regard to whether the prescription is 340B-eligible. *Second*, *after* the unit is dispensed—often weeks or even months later—the covered entity or a for-profit middleman on its behalf determines whether the prescription was 340B-eligible[1]; these middlemen, incentivized by lucrative fees and their financial relationships with covered entities, often falsely determine prescriptions to be 340B-eligible. *Third*, if the prescription is determined to have been 340B-eligible, the covered entity accumulates the units until they reach a full package size and purchases a replacement package at the 340B price, reasoning that it is entitled to be made whole for the 340B price on the dispensed units and that it, at its own election, can choose to be made whole through an in-kind rebate, namely, the purchase of a replenishment package at the 340B price. *Fourth*, the replenishment unit is placed in the common inventory, and the cycle restarts, with the replenishment unit later dispensed without regard to whether the prescription is 340B-eligible. But because the replacement unit was purchased at the 340B price, the subsequent dispensing of the unit when it is not 340B-eligible violates the 340B statute.

42. A defining characteristic of the product replenishment model is that covered entities no longer determine whether a prescription is 340B-eligible *before* it is dispensed. They instead do so after the fact. The model's reliance on after-the-fact 340B eligibility determinations means that 340B Program participants can no longer have any confidence that a 340B-purchased unit will be dispensed only where a prescription is 340B-eligible.

[1] *See* Letter from Sen. Bill Cassidy to Karen S. Lynch, President & CEO of CVS Health at 2 (Jan. 17, 2024) ("[C]overed entities often use third-party administrators (TPAs), like CVS' Wellpartner (Wellpartner), to determine eligibility and process 340B-eligible claims.") (https://www.help.senate.gov/imo/media/doc/340b_cvs_letter.pdf).

43. The product replenishment model imposes greater administrative burdens on manufacturers and drains resources better spent on researching and developing new patient therapies. BMS never agreed to use this problematic model as a condition of participation in the 340B Program, but it has been forced to go along with it given HHS's acquiescence.

44. The shift away from the physical inventory model transforms a mandate to use a 340B discount model into a mandate to offer 340B pricing where, by law, none is owed. Although no pricing model can assure perfect program integrity, a discount model is an especially poor instrument for promoting statutory compliance because there is no requirement to demonstrate eligibility before or even after accessing the (significant) 340B discount. The checks of the physical inventory model provide some assurance of compliance, but the replenishment model provides no similar assurance and instead by its nature leads to 340B pricing on 340B-ineligible prescriptions. It is axiomatic that an agency may not impose requirements in excess of those authorized by statute. HHS's mandated use of a discount model does exactly that by effectively mandating 340B pricing where none is owed.

45. The 340B Program's post-sale audit and administrative dispute resolution (ADR) processes do not mitigate the concern. 89 Fed. Reg. 28,643, 28,646, 28,650 (Apr. 19, 2024). To restore the greater confidence in the propriety of each 340B prescription that the physical inventory model provided, a manufacturer would have to undertake the expense and hassle of after-the-fact audits—of each sale, of each covered outpatient drug, by each covered entity, in perpetuity—as well as ADR proceedings whenever an audit found MDRP-340B duplication or 340B diversion. *See* 42 U.S.C. § 256b(d)(3)(A) (requiring a manufacturer to audit a covered entity before it may initiate an ADR proceeding); 61 Fed. Reg. 65,405, 65,409 (Dec. 12, 1996) (precluding a manufacturer from auditing a covered entity unless it has documentation of reasonable cause). No

manufacturer can do that, the 340B Program does not require it, and the audits and ADR proceedings would overwhelm the savings from ensuring program compliance. A 340B rebate model is a commonsense operational solution that will efficiently address both covered entities' abuses and the burdens currently required to check covered entities' abuses.

The "Drug Price Negotiation Program"

46. The Inflation Reduction Act of 2022 established the "Drug Price Negotiation Program" (DPNP) under which the Secretary of HHS is empowered to set a "maximum fair price" (MFP) to be paid for specified Medicare units of certain drugs. The DPNP statute includes an MFP-340B nonduplication prohibition, creating an inextricable link between the two programs. HHS has authorized manufacturers to use a rebate model to fulfill their obligation to provide access to the MFP. HHS also has directed manufacturers to obtain the data needed to ensure that the MFP-340B nonduplication provision is effectuated.

47. The DPNP statute guarantees MFP-340B nonduplication: A manufacturer is obligated to provide only the lower of the MFP or the 340B ceiling price, not both. 42 U.S.C. § 1320f-2(d). But the provision pairs its nonduplication protection with a compliance obligation: The manufacturer risks a significant civil monetary penalty (CMP) if it does not provide the correct price. *Id.* § 1320f-6 (MFP CMPs); *id.* § 256b(d)(1)(B)(vi) (340B CMPs). And the nonduplication provision limits what otherwise would be the scope of the 340B pricing obligation, rendering it provision an integral component of the overall 340B administrative scheme.

48. Like the 340B statute, the DPNP statute does not specify whether the MFP is to be provided via an up-front discount or an after-the-fact rebate. Recognizing the significant risk of MFP diversion presented by the up-front discount model, HHS has explained that a manufacturer, at its election, may provide the MFP via a rebate. Ctrs. for Medicare & Medicaid Servs. (CMS),

Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Section 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 at § 40.4 (Oct. 2, 2024) (https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf).

49. In doing so, HHS has provided that an MFP rebate must be paid within a 14-day window, which starts when HHS's contractor sends the manufacturer certain claims data that are intended to enable the manufacturer to verify MFP eligibility. *Id.* If the manufacturer does not timely pay the MFP rebate, it risks a substantial CMP equal to ten times the amount of the overcharge above the MFP for each MFP-eligible unit. 42 U.S.C. § 1320f-6(a).

50. MFP-340B nonduplication can be effectuated only if a unit is timely identified as 340B. HHS nevertheless has provided no meaningful mechanism to allow manufacturers to identify which prescriptions are 340B-eligible. CMS, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Section 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 at 231 ("CMS will not, at this time, assume responsibility for nonduplication of discounts between the 340B ceiling price and MFP."); *see also id.* at 54 ("Neither CMS nor [its contractor] will verify that a claim was or was not billed as a 340B-eligible drug."). HHS has declined to mandate use of a 340B claim identifier. *Id.* at 54 ("CMS is not mandating that dispensing entities add a 340B claim indicator to claims at this time."). And HHS has clarified that a provider's status as a covered entity, standing alone, is insufficient to identify a unit as 340B. *Id.* at 230. Yet HHS has specified that a manufacturer may not deny an MFP rebate on account of MFP-340B duplication in the absence of documented identification of the unit as 340B. *Id.*

51. Ultimately, HHS has charged manufacturers to come up with a mechanism to identify 340B units, and thereby enforce MFP-340B nonduplication, on their own. *Id.* at 232 ("CMS strongly encourages manufacturers to work with dispensing entities, covered entities and their 340B TPAs, and other prescription drug supply chain stakeholders (e.g., wholesalers) to facilitate access to the lower of the MFP and the 340B ceiling price, wherever applicable.").

52. Fulfilling this charge in the context of the product replenishment model is untenable, because the model identifies a unit as 340B only after it has been dispensed, and well after the 14-day MFP payment deadline mandated by HHS. This means that the product replenishment model, which is the predominant model used by covered entities today, makes it impossible to identify a unit as 340B-eligible by HHS's deadline for doing so.

BMS's Intended 340B Rebate Model

53. To remedy the rampant noncompliance with the 340B statute's prohibition against MDRP-340B duplication, redress 340B replication, and ensure MFP-340B nonduplication, BMS advised HHS of its plan to implement a 340B rebate model beginning early 2025.

54. BMS's intended 340B rebate model would be fully compliant with both the 340B statute and the PPA.

55. BMS intends to rely on the Second Sight Solutions Beacon platform to operationalize the model.

56. Under the model, covered entities would purchase covered outpatient drugs at commercial prices and submit data to the Beacon platform to demonstrate a dispensed unit's eligibility for the 340B price.

57. BMS intends to remit rebates to covered entities no more than seven to ten days after completed data submission. Where the covered entity agrees to share the 340B price directly with the patient, BMS intends to remit the rebate to the covered entity even faster.

58. BMS intends to offer a 340B rebate at either the dispensed unit or the full package size upon receipt of covered entity data submission. In this way, BMS's intended 340B rebate model could enable covered entities to access the 340B price on a dispensed eligible unit or eligible package faster than they currently do under the product replenishment product, which by necessity requires the purchase of a full replacement saleable unit.

59. At least to start, BMS intends to implement the model exclusively as to its Eliquis® product, which is the company's only product currently subject to an MFP, and to do so with respect to all covered entity types. In this way, the model would enable BMS to timely comply with HHS's charge to identify whether a unit of Eliquis is subject to the 340B price or not, and then issue a rebate based on the lesser of the MFP or the 340B price.

60. BMS plans to implement the model in the spring of 2025. This would enable BMS to gain invaluable experience with the model before submitting its MFP effectuation plan, as required under the DPNP, by the September 1, 2025 deadline.

61. In addition to using the submitted data to support DPNP compliance, BMS would use the data to identify 340B units as to which state Medicaid programs have submitted MDRP rebate claims. With respect to these units, BMS would deny the MDRP rebate claim by the state Medicaid program and honor the 340B rebate claim by the covered entity.

62. Also, where the submitted data indicate that more than one covered entity has requested a 340B rebate on the same unit, BMS would work with the claiming covered entities to determine which one should receive the 340B rebate payment.

HHS's Disapproval of BMS's Intended 340B Rebate Model

63. On October 22, 2024, BMS met with HHS to discuss BMS's intention to pilot its intended 340B rebate model in the spring of 2025.

64. During the meeting, BMS described its intended model and explained how the model would work collaboratively with covered entities to further the interests of the 340B Program. BMS further explained to HHS that the product replenishment model is unsustainable and has undermined program's intent and requirements and that the DPNP requires MFP-340B nonduplication. BMS requested a response by November 4, 2024.

65. On October 24, 2024, BMS followed up with a letter accompanied by supporting documents to respond to HHS's request during the meeting that BMS identify the data to be submitted under the model, as well as to further explain the model and the legal and policy reasons supporting it.

66. In the letter and accompanying documents, BMS explained that the agency has long permitted 340B rebate models, without pre-approval; recounted the well-documented abuses within the 340B Program; outlined the statutory intersection with the DPNP; and described in detail BMS's intended rebate model and its implementation framework, including the legal basis permitting the model. BMS reiterated its request for a response by November 4, 2024.

67. On November 4, 2024, HHS sent a letter to BMS (attached as Exhibit A) in which it declined to approve BMS's intended 340B rebate model: "To date, the Secretary has not provided for . . . a rebate model. Therefore, implementing such a proposal at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval of a rebate model such as BMS has proposed." Ex. A.

68. Despite declining to approve the model, HHS requested additional information about BMS's plans.

69. On November 12, 2024, and in the interest of continuing to work collaboratively with HHS, BMS fully responded to HHS's request for additional information. In doing so, BMS reiterated that HHS does not have the power to require pre-approval of a rebate model. BMS also asked whether there was *any* rebate model that HHS would approve and stated that, if HHS did not respond by November 27, 2024, BMS would understand HHS to maintain its position that *no* rebate model was permissible.

70. On November 21, 2024, HHS responded to BMS's letter but declined to revisit its disapproval of BMS's intended 340B rebate model. HHS stood by its November 4, 2024 determination, repeating that as HHS "has previously stated," if BMS proceeded with "implementing a rebate proposal without Secretarial approval," BMS "would violate Section 340B(a)(1) of the Public Health Service Act." HHS's response was consistent with its past position that the agency "only recognizes a rebate option for the State AIDS Drug Assistance Programs that receive assistance under Title XXVI of the PHS Act" because the agency "agree[d]" that it should "not consider any further expansion to other categories of entities." 63 Fed. Reg. at 35,241–42.

71. BMS's understanding of HHS's position on the 340B rebate model is further informed by HHS's contemporaneous public statements that a manufacturer may not implement a 340B rebate model on pain of, among other things, termination of its PPA—and, as a consequence, termination of federal payment for its covered outpatient drugs under Medicaid and Medicare Part B. Letter from HRSA to Johnson & Johnson (J&J) (Sep. 17, 2024) ("[I]f J&J proceeds with implementing its rebate proposal without Secretarial approval, it will violate section 340B(a)(1)

of the Public Health Service Act. If J&J has not notified HRSA that it is ceasing implementation of its rebate proposal by September 30, 2024, HRSA will begin the process outlined in J&J's Pharmaceutical Pricing Agreement related to terminating the agreement. In addition, if J&J moves forward with implementation of its rebate proposal, HRSA will initiate a referral to the HHS Office of Inspector General pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi).") (https://www.hrsa.gov/sites/default/files/hrsa/opa/sept-27-24-hrsa-letter-johnson-johnson.pdf); *see also* Letter from HRSA to J&J (Sep. 17, 2024) (https://www.hrsa.gov/sites/default/files/hrsa/opa/sept-17-2024-hrsa-letter-johnson-johnson.pdf).

HHS's Disapproval of BMS's Intended 340B Rebate Model Is Unlawful

72. HHS's disapproval of BMS's intended 340B rebate model is unlawful for multiple reasons.

No agency approval is needed for BMS to proceed with its intended 340B rebate model

73. BMS's intended rebate model is fully compliant with both the 340B statute and the PPA. Under the statute, PPA, and past HHS practice, no agency approval is needed for BMS to proceed with its intended rebate model.

74. The text and history of the 340B statute contemplate that 340B pricing may be effectuated via either a discount or a rebate. 42 U.S.C. § 256b(a)(1), (2), (5)(A) (contemplating a "rebate" or "rebates"); H.R. Rep. No 102-384, 102d Cong., 2d Sess., pt. 2 at 16 (1992) ("The [340B] 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.").

75. HHS itself has long acknowledged that there is no statutory default between a discount model and a rebate model. HHS has admitted that "[s]ection 340B has no explicit

language as to whether the required reduction in price should be obtained by an initial reduction in the purchase price (i.e., a discount mechanism) or received as a required reduction in cost rebated after purchase, dispensing, and payment are completed (i.e., a rebate option),” and has quoted the legislative history for the proposition 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,’” 62 Fed. Reg. 45,823, 45,824 (Aug. 29, 1997) (quoting H.R. Rep. No 102-384, 102d Cong., 2d Sess., pt. 2 at 16 (1992)).

76. Moreover, neither the PPA nor any regulation purports to mandate the use of a discount model.

77. A manufacturer is therefore free to implement 340B pricing through either a discount or a rebate.

HHS’s disapproval of BMS’s intended 340B rebate model is unlawful, arbitrary, and capricious

78. Even if HHS pre-approval were required, HHS’s disapproval of BMS’s intended 340B rebate model is unlawful, arbitrary, and capricious for multiple reasons.

79. *First*, HHS may not force manufacturers to offer 340B pricing when it is not required.

80. An HHS mandate that manufacturers use a 340B discount model forces manufacturers to offer 340B pricing when the statute does not require it. HHS cannot lawfully require manufacturers to offer something that section 340B does not. But mandating the use of a discount model does just that.

81. *Second*, the agency may not deny BMS’s intended 340B rebate model the same treatment that it affords the product replenishment model because there is no material difference between the two.

82. The product replenishment model is in fact a form of a rebate model: It is a retrospective model under which 340B eligibility is determined—and 340B pricing is effectuated—after the fact. That is the hallmark of an after-the-fact rebate model, not an up-front discount model. For this reason, HHS cannot object that, under BMS's intended rebate model, covered entities do not receive up-front 340B pricing on a 340B-eligible unit: The same is true under the prevailing product replenishment model. That 340B pricing is effectuated via after-the-fact product replenishment, as opposed to an after-the-fact cash rebate, is immaterial.

83. HHS's differential treatment of the two models could not be more stark. The agency's publicly stated position is that, in the absence of formal pre-approval, a 340B rebate model is subject to the most extreme form of enforcement—termination of a manufacturer's PPA. *See* Letter from HRSA to J&J (Sep. 17, 2024); *see also* Letter from HRSA to J&J (Sep. 17, 2024).

84. Yet the product replenishment model was not formally pre-approved, and the agency acknowledges its existence and countenances its use. *See, e.g.*, HRSA, 340B Peer-to-Peer Program: 340B Compliance Improvement Guide at 36–37 (Oct. 1, 2015). That differential treatment undermines, rather than promotes, statutory compliance: BMS's intended 340B rebate model would materially enhance program integrity, while the product replenishment model, by perpetuating 340B pricing on ineligible units, necessarily undermines it.

85. *Third*, the agency may not treat BMS's intended 340B rebate model and the ADAP rebate model differently because there is no material difference between the two.

86. In guidance purporting to authorize the 340B rebate model only with respect to ADAPs, the agency sought to justify its line-drawing by reference to ADAPs' "unique" needs. 63 Fed. Reg. at 35,241. The agency's most recent discussion of these needs, however, demonstrates that they now equally justify extension of the model to all covered entity types.

87. The agency's most recent ADAP manual describes the ADAP rebate model, explaining that "ADAPs submit claims to drug manufacturers for rebates on medications that were purchased through a retail pharmacy network at a price higher than the 340B price." HRSA, AIDS Drug Assistance Program (ADAP) Manual at 42 (June 2023) (https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/resources/adap-manual.pdf). In other words, the agency recognizes the need for a rebate model with respect to ADAPs when that covered entity type purchases drugs at the commercial price and must reconcile the purchase price with the 340B ceiling price. That need may have been unique to ADAPs back in 1998, but that is no longer the case today.

88. A rebate model is *exactly* the same with respect to *any* type of covered entity that uses the product replenishment model: Under a rebate model, covered outpatient drugs are purchased at the commercial price, and the covered entity needs to reconcile its commercial purchase price with the 340B ceiling price. There is no reasoned basis for limiting the 340B rebate model to ADAPs under even the agency's own stated rationale.

89. Moreover, the ADAP rebate model also is not specified in the PPA and also was not *pre*-approved by HHS; HHS sanctioned it after the ADAP rebate model had already been in effect. *See* 63 Fed. Reg. at 35,240 ("ADAPs may *continue* to provide utilization data according to terms of *existing* agreements if so desired.") (emphasis added).

90. Notably, HHS has made clear that, in effectuating the ADAP rebate model, "standard business practices," including those regarding data reporting, may (and, indeed, should) be followed. *Id.* at 35,239, 35,240, 35,241. And with respect to data reporting, HHS encouraged ADAPs "to consider that the more detailed and accurate the initial claim data, the less likelihood a claim will be questioned or disputed." *Id.* at 35241.

91. This is fully consistent with the agency's longstanding recognition that, more generally, manufacturers may apply standard business practices, including those regarding data reporting, to 340B transactions. *See* 59 Fed. Reg. 25,110, 25,114 (May 13, 1994) (permitting "provisions that address customary business practice, request standard information, or include other appropriate contract provisions"). It is also consistent with courts' confirmation that reasonable conditions, including those regarding data reporting, may attach to an offer of 340B pricing. *See, e.g.*, *Novartis Pharms. Corp.*, 102 F.4th at 461; *Sanofi Aventis*, 58 F.4th at 705. And BMS's intended 340B rebate model, including its data-reporting procedures, is fully consistent with the company's standard business practices.

92. *Fourth*, HHS's disapproval of the 340B rebate model must be considered in light of the totality of the interlocking statutory provisions that constitute the overall 340B administrative scheme. HHS may not charge manufacturers with effectuating MFP-340B nonduplication but disapprove the only operationally feasible model for accomplishing this task—a 340B rebate model. Under the DPNP, HHS has not provided for any meaningful mechanism to identify 340B units and thereby enable manufacturers to effectuate the statutory guarantee of MFP-340B nonduplication. HHS has instead told manufacturers to figure it out themselves. The *only* mechanism available to manufacturers is the 340B rebate model. Yet under the 340B Program, HHS has disapproved a rebate model. Putting manufacturers in this impossible bind is the height of arbitrariness and capriciousness.

93. The DPNP statute guarantees that participating manufacturers do not have to provide both the MFP and 340B pricing on the same prescription. HHS's siloed administration of the DPNP and the 340B Program has rendered this guarantee an impossibility. Indeed, it is so irrational as to violate due process. Given HHS's charge to manufacturers to devise a mechanism

to identify 340B units in order to effectuate MFP-340B nonduplication, HHS cannot disapprove the one tool manufacturers have to meet that charge.

COUNT I
(Administrative Procedure Act, 5 U.S.C. §§ 700, *et seq.*)

94. Plaintiff re-alleges and incorporates by reference the allegations in the foregoing numbered paragraphs.

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

96. HHS's disapproval of BMS's 340B rebate model contravenes the plain language of the 340B statute and the PPA and is therefore in excess of the agency's statutory authority and unlawful under the APA. The statute contemplates that 340B pricing may be effectuated through either a discount or a rebate. 42 U.S.C. § 256b(a)(1), (2), (5)(A). Nothing in any statute or regulation or in the PPA requires 340B pricing via a discount. BMS is therefore free to offer 340B pricing through either a discount or a rebate.

97. HHS's disapproval of BMS's intended 340B rebate model constitutes final agency action for which BMS has no other adequate remedy at law.

COUNT II
(Administrative Procedure Act, 5 U.S.C. §§ 700, *et seq.*)

98. Plaintiff re-alleges and incorporates by reference the allegations in the foregoing numbered paragraphs.

99. HHS's disapproval of BMS's intended 340B rebate model is arbitrary and capricious, lacks a logical basis, and constitutes an abuse of discretion. *See* 5 U.S.C. § 706(2)(A).

100. *First*, a mandate by HHS that manufacturers rely solely on a 340B discount model forces manufacturers to offer 340B pricing where, by the plain terms of the 340B statute, none is owed. HHS cannot lawfully require manufacturers to offer 340B pricing when 340B pricing is not statutorily required. Mandating the use of a discount model is patently unlawful, arbitrary, and capricious.

101. *Second*, HHS has acted arbitrarily and capriciously by treating BMS's intended 340B rebate model differently from the product replenishment model even though there is no material difference between the two.

102. Moreover, HHS's differential treatment is illogical to the point of being arbitrary and capricious because it undermines, rather than promotes, statutory compliance. BMS's intended 340B rebate model would materially enhance program integrity, while the product replenishment model—by perpetuating 340B pricing on ineligible units—necessarily undermines it.

103. *Third*, HHS has acted arbitrarily and capriciously by treating BMS's intended 340B rebate model differently from the ADAP rebate model even though there being no material difference between the two. A rebate model is *exactly* the same with respect to *any* type of covered entity that uses the product replenishment model: Under a rebate model, covered outpatient drugs are purchased at the commercial price and the commercial price is later reconciled with the 340B ceiling price. There is no reasoned basis for limiting the 340B rebate model to ADAPs under even the agency's own stated rationale.

104. *Fourth*, HHS may not direct manufacturers to ensure MFP-340B nonduplication but disapprove the 340B rebate model. HHS has not provided under the DPNP for any meaningful mechanism to identify 340B units and thereby enable manufacturers to effectuate the statutory

guarantee of MFP-340B nonduplication. Instead, HHS has told manufacturers to figure it out for themselves. The *only* mechanism available to manufacturers is the 340B rebate model. But HHS has refused to allow BMS and other manufacturers to implement that model. Putting manufacturers in this impossible bind is the height of arbitrary and capricious action.

COUNT III
(Due Process Clause, U.S. Const. amend. V)

105. Plaintiff re-alleges and incorporates by reference the allegations in the foregoing numbered paragraphs.

106. The Due Process Clause of the Fifth Amendment to the United States Constitution guarantees that no person shall be subject to governmental deprivation of life, liberty, or property without due process of law.

107. The DPNP statute guarantees that participating manufacturers should not have to provide both MFP and 340B pricing on the same prescription. HHS's siloed administration of the DPNP and the 340B Program has rendered this guarantee an impossibility. Putting manufacturers in this impossible bind is so irrational as to impinge on the constitutional guarantee of substantive due process. Given HHS's direction that manufacturers devise a mechanism to identify 340B units in order to prevent MFP-340B duplication, HHS cannot lawfully disapprove of the 340B rebate model.

PRAYER FOR RELIEF

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

A. A declaration under 28 U.S.C. § 2201 that the agency's position regarding the 340B rebate model is unlawful;

B. An order vacating and setting aside HHS's disapproval of BMS's rebate model on the grounds that it is unlawful, arbitrary, and capricious;

C. Temporary, preliminary, and permanent injunctive relief barring Defendants and any entities acting in concert with them from initiating or pursuing any enforcement actions against BMS in connection with its 340B rebate model;

D. An order awarding BMS its costs, expenses, and attorneys' fees incurred in these proceedings pursuant to 28 U.S.C. § 2412; and

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

Respectfully submitted,

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