UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHNSON & JOHNSON HEALTH CARE SYSTEMS INC., Plaintiff,		
v.		
ROBERT F. KENNEDY, JR., Secretary of Health and Human Services, *et al.*, Defendants,	Civil Action No.:	24-3188 (RC)
and	Re Document Nos.:	18, 21, 22, 23, 25 28, 33, 38, 39, 41 54
340B HEALTH, *et al.*, Intervenor-Defendants.		

MEMORANDUM OPINION

RESOLVING THE PARTIES' MOTIONS FOR SUMMARY JUDGMENT

I. INTRODUCTION

In November 2024, Plaintiff Johnson & Johnson Health Care Systems Inc. ("J&J") filed suit against the Department of Health and Human Services ("HHS"), HHS's Health Resources and Services Administration ("HRSA"), and the heads of those agencies[1] regarding the 340B Drug Pricing Program, 42 U.S.C. § 256b. The 340B Program requires pharmaceutical drug manufacturers that participate in Medicaid and Medicare Part B, like J&J, to sell drugs to certain statutorily covered healthcare providers at lower prices. J&J sells drugs to covered entities at a discount. But in June 2024, J&J contacted HRSA to discuss J&J's plan to implement a rebate model, whereby covered entities would purchase certain drugs at full price and receive a rebate

[1] Pursuant to Federal Rule of Civil Procedure 25(d), these officials have been substituted for their successors.

at a later date. After HRSA informed J&J that it had not approved its rebate model, J&J sued. In January 2025, two hospitals that receive benefits under the 340B program, UMass Memorial Medical Center ("UMass") and Genesis HealthCare System ("Genesis"), and an organization that advocates for covered entities, 340B Health (collectively, "Intervenors"), filed a motion to intervene as defendants. The Court granted that motion. Plaintiff J&J has moved for summary judgment on its single cause of action brought under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706. Defendants and Intervenors filed cross motions for summary judgment. The parties' summary judgment motions are now fully briefed. For the reasons stated below, J&J's motion for summary judgment is denied, and Defendants' and Intervenors' motions for summary judgment are granted.

II. BACKGROUND

A. Statutory and Regulatory Background

In 1992, Congress enacted Section 340B as an amendment to the Public Health Service Act. Veterans Health Care Act of 1992, Pub. L. No. 102-585 § 602, 106 Stat. 4943, 4967–71. Section 340B "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011). To encourage manufacturer participation, Congress conditioned coverage of a manufacturer's products under Medicaid and Medicare Part B on participation in the 340B Program. 42 U.S.C. § 1396r-8(a)(1), (5).

In 2010, the Affordable Care Act amended Section 340B by "expand[ing] the list of covered entities eligible to participate in the program and add[ing] several new provisions aimed at improving compliance with program requirements." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 455–56 (D.C. Cir. 2024) (citing Pub. L. No. 111-148, tit. VII, §§ 7101–02, 124 Stat.

119, 821–27). That amendment also added the requirement that manufacturers must "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." Pub. L. No. 111-148, tit. VII, §§ 7102, 124 Stat. 119, 827; 42 U.S.C. § 256b(a)(1). This provision has been interpreted to require that manufacturers make a "bona fide offer," a limitation on the conditions manufacturers can impose when offering their 340B drugs for sale. *See Novartis*, 102 F.4th at 462.

The 340B Program "was intended to enable certain hospitals and clinics 'to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'" *Am. Hosp. Ass'n v. Hargan*, 289 F. Supp. 3d 45, 47 (D.D.C. 2017) (quoting H.R. Rep. 102-384, pt. 2, at 12 (1992)). Since the early years of the 340B Program, HRSA has recognized that "Section 340B does not limit the pricing behavior of covered entities." Notice Regarding Section 602 of the Veteran Health Care Act of 1992, 61 Fed. Reg. 43549, 43551 (Aug. 23, 1996). "While some may pass all or a significant part of the discount to their patients, others may set the price slightly higher than the actual acquisition cost plus a reasonable dispensing fee, using the savings [i.e., profits] to reach more eligible patients and provide more comprehensive services." *Id.*

"Drug manufacturers opt into the 340B Program by signing a form Pharmaceutical Pricing Agreement (PPA) used nationwide." *Astra*, 563 U.S. at 113. These PPAs are "not transactional, bargained-for contracts," but are "uniform agreements that recite the responsibilities § 340B imposes." *Id.* Under the statute, "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 . . . [must] not exceed an amount equal to" a "ceiling price," the formula for which is provided in the statutory scheme. 42 U.S.C.

§ 256b(a)(1). As mentioned, this pricing rule applies to all covered drugs "made available to any other purchaser at any price." *Id.*

Congress identified two potential misuses of the 340B Program: duplicate discounts, 42 U.S.C. § 256b(a)(5)(A), and diversions, *id.* § 256b(a)(5)(B). *See* H.R. Rep. No. 102-384, pt. 2, at 16–17 (1992). Duplicate discounts occur when a covered entity receives a discount or rebate for a unit of a drug under the 340B Program and a rebate under a Medicaid program. 42 U.S.C. § 256b(a)(5)(A). Diversions occur when drugs are sold or transferred "to a person who is not a patient of the entity," thereby defeating the purpose of affording the covered entity the benefit of that status, such as providing "safety-net services to the poor." *Id.* § 256b(a)(5)(B); *Astra*, 563 U.S. at 113.

To "assure the integrity of the drug price limitation program," including these prohibitions, Congress provided for "auditing" by the Agency or drug manufacturers as a "requirement[] for covered entities." H.R. Rep. No. 102-384, pt. 2, at 16; 42 U.S.C. § 256b(a)(5)(C). Noncompliance with the prohibitions against duplicate discounts and diversions is sanctionable, including with liability to the manufacturer for underpayment for the drugs. *Id.* § 256b(a)(5)(d). Sanctions are levied "after audit as described in subparagraph (C) and after notice and hearing." *Id.* And "[i]f a dispute concerning the audit findings and recommendations arises, the parties may file a request for dispute resolution" with HRSA. Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65406, 65410 (Dec. 12, 1996). Similarly, HHS has provided a process for adjudicating claims that a covered entity has been overcharged by a manufacturer. *See* 42 C.F.R. § 10.21(a).

B. 340B in Practice

Since its inception, covered entities have primarily received the benefit of the lower prices guaranteed by the 340B Program through up-front discounts. *See* Defs.' Mem. of P. & A. in Supp. of Cross Mot. for Summ. J. ("Gov't MSJ") at 3, ECF No. 41-1. One exception to this norm occurred in 1998 when HRSA published guidance allowing for rebates for drugs sold to AIDS Drug Assistance Programs ("ADAPs"), but HRSA explicitly limited its guidance to ADAPs at that time. Notice Regarding Section 602 of the Veterans Health Care Act of 1992—Rebate Option, 63 Fed. Reg. 35239, 35241–42 (June 29, 1998). While discounts have consistently dominated, the processing of those discounts has changed in two major ways.

First, covered entities often outsource distribution of drugs to outside pharmacies, also known as "contract pharmacies." *See Novartis*, 102 F.4th at 455, 457. Though HRSA issued guidance in 1996 permitting each covered entity to contract with a single outside pharmacy to dispense drugs at a single location, in 2010, HRSA "swerved" and "opined that covered entities may contract with an unlimited number of outside pharmacies." *Id.* at 456–57 (comparing 61 Fed. Reg. at 43549–50, with Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272, 10272–73 (Mar. 5, 2010)). Since 2010, use of contract pharmacies has rapidly increased. *See* 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://www.gao.gov/assets/gao-20-212.pdf (noting an increase in contract pharmacies "from about 1,300 at the beginning of 2010 to around 23,000 in 2019").

Second, covered entities have widely adopted a "replenishment model" to purchase discounted drugs. *See Novartis*, 102 F.4th at 457. "While some contract pharmacies maintain

separate inventories of section 340B drugs, most fill prescriptions from inventories that intermingle discounted and non-discounted drugs." *Novartis*, 102 F.4th at 457. This method has been blessed by HRSA since at least 1996. *See* 61 Fed. Reg. at 43554 (describing the requirement of a separate inventory as a "wasteful concept with respect to time, space and money" because the "covered entity is required to monitor dispensing and inventory records"). Under this model, the drug inventory is typically purchased at full price, and then, after the covered entity dispenses, or "accumulates," a package worth of units of a discount-eligible 340B drug, the covered entity purchases another package to "replenish" its inventory at the discounted 340B price. *See* AR 60, 196, 203; Compl. ¶ 12, ECF No. 1; Brief of 340B Health, UMass Memorial Medical Center, and Genesis HealthCare System ("Intervenors' MSJ") at 8–10, ECF No. 53.

C. Factual and Procedural Background

J&J has previously participated in the 340B Program by offering covered entities drugs at discounted prices. Compl. ¶¶ 2, 78. Under the discount model status quo, J&J contends that "abuse of the 340B program by covered entities has become rampant and well documented." Mem. in Supp. of Pl.'s Mot. for Summ. J. ("J&J MSJ") at 11, ECF No. 18-1. In 2024, J&J noticed significant increases in 340B utilization. J&J MSJ at 13; AR 157. J&J sought to audit several covered entities that had sizable increases in their 340B purchasing, and those audits were the subject of a collection of related cases before this Court. *See, e.g.*, *Or. Health & Sci. Univ. v. Engels*, No. 24-cv-2184, 2025 WL 1707630 (D.D.C. June 17, 2025).

As the audit dispute was beginning, J&J moved forward with developing "a rebate model to effectuate 340B pricing." J&J MSJ at 14. J&J met with HRSA on July 24, 2024 to discuss its "Rebate Model Solution." *See* AR 154, 156. J&J raised concerns that "it has little to no

visibility into the claim-level data necessary to validate 340B claims," and that it was facing challenges with upcoming obligations that would be imposed when relevant provisions of the Inflation Reduction Act ("IRA"), Pub. L. No. 117-169, 136 Stat. 1818 (2022),[2] become effective in 2026. J&J MSJ at 15; AR 157, 166–67. HRSA requested that J&J submit its "legal support for the rebate model," which J&J did on July 31, 2024, in a letter that also provided details about its rebate model. AR 55–63. Under J&J's rebate model, covered entities would purchase products at wholesale acquisition cost, and rather than accumulating claims to place a replenishment order, would submit a rebate claim on J&J's platform. AR 60. J&J anticipates that the data it requires would "be information the covered entity already collects and keeps in the normal course of business" and that it would be able to pay valid rebated claims within ten days of submission. AR 61. J&J intended to implement its rebate model for two of its drugs, STELARA and XARELTO, starting on October 15, 2024. AR 62.

But that plan was thwarted. On August 14, 2024, HRSA sent J&J a letter explaining that "[t]o date, the Secretary ha[d] not provided for such rebate as proposed by J&J" and that "implementing such a proposal at this time would be inconsistent with the statutory requirements for the 340B Program." AR 66. HRSA also posed a series of questions about J&J's rebate model. *See* AR 66–68. Two days later, J&J responded, disagreeing with HRSA's statutory interpretation and answering HRSA's questions. AR 72–84. J&J further responded to HRSA's August 14 letter on September 12, 2024. AR 191–200.

[2] The IRA will require manufacturers to sell certain drugs for Medicare beneficiaries at or below a "maximum fair price" negotiated with the Secretary (or his delegate). 42 U.S.C. §§ 1320f(c)(2), 1320f-2(a). If a dispensed drug is eligible for a reduced price under both the IRA and the 340B Program, then the covered entity is entitled to the lower price of the two. *Id.* § 1320f-2(d). Duplicate discounts are prohibited. *Id.* § 1320f-(2)(d)(2).

On September 17, 2024, HRSA responded by letter,[3] reiterating its prior position that J&J could not implement its rebate model without prior approval. AR 202. HRSA also distinguished J&J's rebate model from replenishment models on three grounds: (1) under a replenishment model, a covered entity typically makes only an initial purchase at a higher price, rather than continually; (2) rebate models are explicitly subject to prior approval under the 340B statute; and (3) covered entities voluntarily choose to use replenishment models. AR 203. HRSA reminded J&J that implementation of its rebate model would violate the 340B statute and could lead to termination of J&J's PPA. AR 203.

J&J responded on September 19, 2024, maintaining its positions. AR 207–11. And on September 27, 2024, HRSA again responded, emphasizing that J&J had not yet requested the required Secretarial approval.[4] AR 214. On September 30, 2024, J&J acquiesced to HRSA's demand not to implement its rebate model, but maintained its positions regarding the need for a rebate model with support including a Government Accountability Office Report noting significant rates of duplicate discounts and diversions in the Program. AR 216–17.

After further communications failed to result in HRSA approval of J&J's rebate model, J&J filed this suit on November 12, 2024, alleging a single claim under the APA. Compl. ¶¶ 130–36. The Complaint seeks declaratory and injunctive relief, and asks the Court to vacate and set aside HRSA's August 14, September 17, and September 27 letters, and declare that J&J's rebate model is lawful under the 340B statute. *Id.* at 49. On January 30, 2025, 340B Health,

[3] HRSA published this letter on its website. *See* HRSA Letter to Johnson and Johnson (Sep. 17, 2024), https://www.hrsa.gov/sites/default/files/hrsa/opa/sept-17-2024-hrsa-letter-johnson-johnson.pdf [https://perma.cc/R677-R2KC].

[4] HRSA also published this letter on its website. See HRSA Response to J&J's September 18, 2024 Letter (Sep. 27, 2024), https://www.hrsa.gov/sites/default/files/hrsa/opa/sept-27-24-hrsa-letter-johnson-johnson.pdf [https://perma.cc/2G74-G42H].

UMass, and Genesis moved to intervene as defendants, and the Court granted that motion. 340B Health, UMass Memorial Medical Center, and Genesis HealthCare System's Mot. to Intervene, ECF No. 14; Order Granting Mot. to Intervene, ECF No. 49.

On February 3, 2025, J&J moved for summary judgment, arguing that HRSA lacks authority to mandate a pricing mechanism under the 340B statute, and that HRSA rejected its rebate model without required procedure and in an arbitrary and capricious way because of its inconsistent treatment of rebate and replenishment models. *See* J&J MSJ at 1–3. Defendants and Intervenors opposed that motion, and cross-moved for summary judgment. *See* Gov't MSJ; Intervenors' MSJ. Defendants argue that the 340B statute requires that HRSA pre-approve a rebate model, and that its position that J&J could not implement its rebate model without Agency approval was not arbitrary and capricious. Gov't MSJ at 1. Intervenors argue that the 340B statute requires discounts rather than rebates and that enforcing this requirement does not violate the APA. Intervenors' MSJ at 14, 31. These motions for summary judgment are now fully briefed and ready for review.

Many 340B Program stakeholders have submitted proposed amicus briefs in this case, and the Court thanks each of them for providing helpful context and additional perspectives.[5] None of these motions is opposed. Because the Court believes that each proposed amicus "has unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide," the Court will grant the motions for leave to file amicus briefs.[6] *See*

[5] These stakeholders include patient advocacy groups, pharmaceutical research and manufacturing associations, and hospital associations.

[6] J&J moves to strike portions of an amicus brief that contain results from a survey of covered entities. *See* Plaintiff's Motion to Strike Portions of Proposed Amicus Brief, ECF No. 39 (moving to strike portions of Amici Curiae Brief of American Hospital Association, National Association of Children's Hospitals, Inc., D/B/A/ Children's Hospital Association, Associations of American Medical Colleges and America's Essential Hospitals in Support of

Jin v. Ministry of State Sec., 557 F. Supp. 2d 131, 137 (D.D.C. 2008) (quoting *Ryan v. CFTC*, 125 F.3d 1062, 1063 (7th Cir. 1997)).

III. LEGAL STANDARD

Under Federal Rule of Civil Procedure 56, a "court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "[H]owever, when a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal" and assesses the entire case as "a question of law." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). When doing so, "it is black-letter administrative law that . . . a reviewing court 'should have before it neither more nor less information than did the agency when it made its decision.'" *Hill Dermaceuticals, Inc. v. Food & Drug Admin.*, 709 F.3d 44, 47 (D.C. Cir. 2013) (quoting *Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984)).

Defendants, ECF No. 33-1). J&J would like these surveys stricken because they "are not part of the Administrative Record for the agency action in this case" and because it believes they "are unreliable and inconsistent with other evidence properly made part of the record." *Id.* at 1–2. These Amici disclaim any attempt to supplement the Administrative Record, and explain that they seek to provide the Court with an important perspective as it applies the legal standard to the record in this case. Proposed Amici's Response to Plaintiff's Motion to Strike Portions of Proposed Amicus Brief that Rely upon Extra-Record Material at 2–3, ECF No. 40. This Court "has broad discretion to allow amicus briefs when they provide 'unique information or perspective' that 'can help the [c]ourt beyond the help that the lawyers for the parties are able to provide.'" *Wash. All. of Tech. Workers v. U.S. Dep't of Homeland Sec.*, 50 F.4th 164, 193 (D.C. Cir. 2022) (alteration in original) (quoting 518 F. Supp. 3d, 448, 453 n.2 (D.D.C. 2021)). When evaluating the Agency's actions in this case, the Court limits its review to the record before the agency. *See Hill Dermaceuticals, Inc. v. Food & Drug Admin.*, 709 F.3d 44, 47 (D.C. Cir. 2013). Because the Court does not rely on the extra-record material and considers this brief only for its unique perspective in this complex area of law, the Court will exercise its discretion to deny J&J's motion to strike. *See Wash. All. of Tech. Workers*, 50 F.4th at 193–94 (affirming district court's denial of motion to strike amicus briefs where the district court did not rely on any material outside the administrative record).

Under the APA, courts can set aside agency actions found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C). "[A]n agency acts arbitrarily or capriciously if it 'has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'" *Am. Wildlands v. Kempthorne*, 530 F.3d 991, 997–98 (D.C. Cir. 2008) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). "Where the question is whether the agency action was consistent with statutory authorization, our task is to determine whether the agency acted consistently with the 'best reading' of the statute." *Vanda Pharms., Inc. v. FDA*, 123 F.4th 513, 521 (D.C. Cir. 2024) (quoting *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 395 (2024)). The court must use all relevant interpretive tools to determine whether the statute "'delegates discretionary authority' to the agency and whether the agency 'engaged in reasoned decisionmaking within [the] boundaries' of that statutory delegation." *Id.* (alteration in original) (quoting *Loper Bright*, 603 U.S. at 395). "In the business of statutory interpretation, if it is not the best, it is not permissible." *Loper Bright*, 603 U.S. at 400.

IV. ANALYSIS

Because the parties dispute the proper interpretation of the 340B statute, the Court first analyzes the text, structure, purpose, and history of that statute. These tools of statutory construction all support Defendants' interpretation: the parenthetical phrase "taking into account any rebate or discount, as provided by the Secretary" gives the Secretary the discretion to

provide for a rebate model, or not. *See* 42 U.S.C. § 256b(a)(1). Next, the Court turns to the legality of HRSA's determination that it had not provided for J&J's rebate model. The Court rejects J&J's argument that the APA required HRSA to conduct notice-and-comment rulemaking to reach its conclusion; rather, HRSA exercised its discretion delegated by the statute when it did not provide for J&J's rebate model here. And similarly, the Court rejects J&J's argument that HRSA acted arbitrarily and capriciously by treating J&J's rebate model and replenishment models differently. Because the two models are completely different mechanisms for effectuating 340B discounts, HRSA's reliance on those differences was neither arbitrary nor capricious. Lastly, the Court is satisfied that HRSA's determination was reasonable and reasonably explained—HRSA was not required to address every concern J&J had raised to determine it had not approved rebates broadly. Because Defendants have the better argument on these points as discussed below, their motion for summary judgment is granted.

A. Statutory Interpretation

The statutory interpretation question in this case is two-fold: (1) Does the 340B statute allow for both rebate and discount models? (2) If so, who has the authority to determine which model should be used? The plain and unambiguous text of the statute answers these questions, "yes, the Secretary."[7]

1. Text and Structure

"Courts must 'interpret statutes, no matter the context, based on the traditional tools of statutory construction.'" *Pac. Gas & Elec. Co. v. FERC*, 113 F.4th 943, 947 (D.C. Cir. 2024) (quoting *Loper Bright*, 603 U.S. at 403). As always, "we begin with the text" and "look to the

[7] The Court notes that another judge in this District has reached the same conclusion in a series of related cases. *See, e.g.*, *Eli Lilly & Co. v. Kennedy*, No. 24-cv-3220 (DLF), 2025 WL 1423630, at *9–11 (D.D.C. May 15, 2025).

ordinary meaning of its key terms." *Id.* at 948 (first quoting *City of Clarksville v. FERC*, 888 F.3d 477, 482 (D.C. Cir. 2018); then quoting *Novartis*, 102 F.4th at 460). And courts "must enforce plain and unambiguous statutory language according to its terms." *Hardt v. Reliance Standard Life Ins. Co.*, 560 U.S. 242, 251 (2010).

Here, the 340B statute provides:

> 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 "ceiling price,"] an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act [Medicaid] in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement . . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

42 U.S.C. § 256b(a)(1) (emphasis added). The parties dispute the meaning of the parenthetical phrase "taking into account any rebate or discount, as provided by the Secretary." *See id.* On one end of the spectrum, J&J argues that HRSA cannot direct a pricing mechanism and that manufacturers retain discretion to choose the pricing mechanism they see fit. J&J MSJ at 1, 36; Pl.'s Br. in Opp'n to Defs.' Cross-Mot. for Summ. J. and Reply in Supp. of Summ. J. ("J&J Reply") at 29, ECF No. 44. On the other end of the spectrum, Intervenors argue that the statute requires that manufacturers use a discount mechanism to effectuate the 340B price. Intervenors' MSJ at 1–2, 14–25. In the middle, Defendants argue that the statute allows the Secretary (through HRSA) to provide for either a rebate or discount model. Gov't MSJ at 8, 13. The text clearly supports Defendants' interpretation.

Based on a plain reading, "as provided by the Secretary" modifies the phrase immediately preceding it, "any rebate or discount." *See* 42 U.S.C. § 256b(a)(1). To "provide" is "to make something available to," or "to have as a condition" or "stipulate." *Provide*, Merriam-Webster's

Collegiate Dictionary 940 (10th ed. 1993); *Provide*, 12 Oxford English Dictionary 713 (2d ed. 1989) (defining "provide" as "[t]o make it, or lay it down as, a provision or arrangement; to stipulate that"). So, the parenthetical means that HRSA can make available to manufacturers—or provide for—rebates, discounts, or both. And when determining the ceiling price to be paid for a 340B drug, that price is not simply the sticker price, but should "tak[e] into account any rebate or discount." *See* 42 U.S.C. § 256b(a)(1).

The phrase "taking into account" causes some confusion for J&J. It argues that the phrase "as provided by the Secretary" modifies "the entire rest of the parenthetical—'taking into account any rebate or discount.'" J&J MSJ at 28 (quoting 42 U.S.C. § 256b(a)(1)). Even were that correct, the result is the same. J&J does not explain why the Secretary, in determining how to take account of any rebate or discount, could not choose to allow for only one or the other. *See, e.g.*, J&J MSJ at 28–29; J&J Opp'n at 12–13. In fact, that discretion would seem to be the exact authority the statute grants the Secretary. After all, no party argues the Secretary, in accounting for a discount, could change the *value* of that discount and effectively change the statutorily provided ceiling price for a drug. *See* J&J Opp'n at 11; Defs.' Reply Further Supp. Mot. Summ. J. ("Gov't Reply") at 3, ECF No. 46; J&J's Second Reply at 6. So then if not the provision, or making available, of either a rebate or discount, what could be taken account of?

J&J responds with a narrow reading of "taking into account," that is limited to how the pricing mechanism is implemented, or even more literally, the types of "accounting records" that must be maintained. J&J MSJ at 29. Though J&J insists that the statute "merely authorizes Defendants to direct in the PPA that manufacturers must use appropriate records, recordkeeping procedures, or accounting mechanisms to account for the rebates or discounts they choose to provide," the statute's text makes no mention of manufacturer recordkeeping or financial

accounting. *See id.* at 27. Fortunately, the Court need not strain to understand the plain text of the statute. The more natural reading of "taking into account" would be "considering." *Consider*, Merriam-Webster's Collegiate Dictionary 246 (10th ed. 1993) (defining "consider" as "to take into account"); *Considered*, 3 Oxford English Dictionary 768 (2d ed. 1989) (defining "considered" as "being taken into account"). And "[considering] any rebate or discount, as provided by the Secretary" clearly means the Secretary has discretion to provide for rebates, discounts, or both. 42 U.S.C. § 256b(a)(1).

Undeterred, J&J and Intervenors each propose constructions that would violate the "cardinal principle of statutory construction that [courts] must 'give effect, if possible, to every clause and word of a statute.'" *Williams v. Taylor*, 529 U.S. 362, 404 (2000) (quoting *United States v. Menasche*, 348 U.S. 528, 538–39 (1955)); *Cares Cmty. Health v. U.S. Dep't of Health & Hum. Servs.*, 944 F.3d 950, 960 (D.C. Cir. 2019) ("[T]he canon against surplusage ensures 'that effect is given to all [statutory] provisions, so that no part will be inoperative or superfluous, void or insignificant.'" (second alteration in original) (quoting *Rubin v. Islamic Republic of Iran*, 583 U.S. 202, 213 (2018))). J&J reads "as provided by the Secretary" out of the statute entirely. Rather, in reading the statute to make manufacturers "free to offer the ceiling price to covered entities via a rebate or discount at [their] discretion," J&J appears to replace "as provided by the Secretary" with "as provided by the *manufacturer*." *See* J&J MSJ at 33; Gov't MSJ at 9. That cannot be right. Unsupported by the text, J&J turns to *Novartis*, *see* J&J MSJ at 33, in which the D.C. Circuit held that "statutory silence implies that private parties may act freely," *Novartis*, 102 F.4th at 460. But that is beside the point; here, the statute's grant of authority to the Secretary is explicit, not silent.

Intervenors, on the other hand, read "rebate" out of the statute, and argue that "[b]ecause manufacturers must offer to sell covered drugs at this maximum ceiling price, any attempt to sell covered drugs to 340B Providers above this price in the first instance would, by definition, run afoul of the statutory language."[8] Intervenors' MSJ at 14, 17. In doing so, they limit the "ceiling price" to the amount paid at the moment of purchase. *See* Intervenor Defs.' Reply in Supp. of Cross Mot. for Summ. J. ("Intervenors' Reply") at 2–3, ECF No. 57. This would seem to render the word "rebate" surplusage because rebates are only paid if the purchaser has initially paid above the ceiling price. *See Williams*, 529 U.S. at 404. To justify this result, Intervenors limit the applicability of the disputed parenthetical to circumstances when the Secretary needs to "make[] adjustments to achieve a 340B discount that is different from the ceiling price calculation in the 340B statute," such as when a drug is new to the market or when the statute's formula results in a 340B price of $0 or less. Intervenors' MSJ at 15. But if Congress intended for the parenthetical to be read so narrowly, it left no clues in the text of that sentence, which establishes the general price-setting function of the 340B Program. This, too, cannot be right.

Defendants have the best interpretation. Based on the plain and unambiguous language of the 340B statute, HRSA has the authority to provide for rebates, or not.

J&J argues in the alternative that "even if HRSA were correct that the best reading of the statute is that the Secretary has discretion to direct a pricing mechanism . . . the *only* regulatory vehicle through which HRSA could possibly implement such a mandate is the PPA." J&J MSJ at 33. But the provision that instructs the Secretary to "enter into an agreement" does not limit how the Secretary can provide for rebates or discounts. If it did, the parenthetical phrase "as

[8] To the extent HRSA took this position in its September 17, 2024 letter to J&J, AR 202–03, HRSA appears to have abandoned it in this litigation, *see* Gov't MSJ at 13–14.

provided by the Secretary" would be rendered surplusage—rebates or discounts would already be "provided by the" PPAs, not the Secretary. Thus, the statute's language does not support J&J's proposed limitation.

Zooming out, J&J notes that the relevant provision appears in a "subsection of the statute . . . titled 'Requirements for agreement with Secretary.'" J&J MSJ at 33 (quoting 42 U.S.C. § 256b(a)). The persuasive effect of this argument is diluted, however, by the relevant provision appearing in a sub-subsection titled, "In general," which J&J fails to mention, let alone explain, in its briefing. *See* 42 U.S.C. § 256b(a)(1). Moreover, as the Supreme Court has recognized, "PPAs are not transactional, bargained-for contracts" but are instead "uniform agreements that recite the responsibilities § 340B imposes." *Astra*, 563 U.S. at 113. To the extent the PPA does change, *see* J&J Opp'n at 28, it does so based on changes to the 340B statute, *see* Gov't Reply at 5–6 (discussing the 2016 PPA Addendum as responding to additional requirements of the Affordable Care Act). While PPAs may include additional terms, as J&J notes, neither the 340B statute's text nor Agency practice—including providing for ADAP rebates through notice and comment, not separate PPAs—limits the Secretary's method of providing for rebates or discounts to PPAs. The better reading is that the statute provides for the requirements of the 340B Program, which is implemented through PPAs, but not exclusively delineated by them. *See, e.g.*, Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65406 (Dec. 12, 1996) (providing procedures for initiating manufacture audits pursuant to 42 U.S.C. § 256b(a)(5)(C), another provision of subsection (a) not exclusively contained in PPAs).

Because the 340B statute's language is plain, the Court's statutory analysis could stop here. *See Lamie v. U.S. Trustee*, 540 U.S. 526, 534 (2004) ("It is well established that 'when the

statute's language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms.'" (quoting *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000))). But even were the Court to consider the statute's purpose and legislative history, those further support the plain meaning of the text.

2. Purpose and History

The 340B program "was intended to enable certain hospitals and clinics 'to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'" *Am. Hosp. Ass'n v. Hargan*, 289 F. Supp. 3d 45, 47 (D.D.C. 2017), *aff'd sub nom. Am. Hosp. Ass'n v. Azar*, 895 F.3d 822 (D.C. Cir. 2018) (quoting H.R. Rep. 102-384, pt. 2, at 12 (1992)). And since its beginning, the 340B price reductions were to be "implemented, at the discretion of the Secretary, either by a point-of-purchase discount, a rebate, or other mechanism." H.R. Rep. 102-384, pt. 2, at 12 (1992); *id.* (stating manufacturers "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"); *see also* Guidance Regarding Section 602 of the Veterans Health Care Act of 1992; Limitation on Prices of Drugs Purchased by Covered Entities, 58 Fed. Reg. 27289, 27290 (May 7, 1993) (stating that the act creating the 340B Program is "an attempt to provide Federal purchasers with a process whereby they will receive drug discounts or rebates"). As the House Report stated:

> 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. A mechanism that is appropriate to one type of "covered entity," such as community health centers, may not be appropriate to another type, such as State AIDS drug purchasing programs. The Committee expects that the Secretary of HHS, in developing these agreements, will use the

> mechanism that is the most effective and most efficient from the standpoint of each type of "covered entity."

H.R. Rep. 102-384, pt. 2, at 16 (1992).[9] This would tend to support the Secretary's discretion.

But the Court need not stop there. "[A]lthough an agency's interpretation of a statute 'cannot bind a court,' it may be especially informative 'to the extent it rests on factual premises within [the agency's] expertise.'" *Loper Bright*, 603 U.S. at 402 (second alteration in original) (quoting *Bureau of Alcohol, Tobacco and Firearms v. FLRA*, 464 U.S. 89, 98, n.8 (1983)). And "the longstanding practice of the government—like any other interpretive aid—can inform a court's determination of what the law is." *Id.* at 386 (cleaned up) (quoting *NLRB v. Noel Canning*, 573 U.S. 513, 525 (2014).

"Initially, HRSA guidance for the section 340B program described only a discount process. Covered entities generally preferred a discount system, because they could negotiate lower prices and needed less initial outlay of drug purchasing money." Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Rebate Option, 62 Fed. Reg. 45823, 45824 (Aug. 29, 1997). But as the statute's House Report expected, HRSA has exercised its authority and expertise to determine "the most effective and most efficient" mechanisms for implementing 340B pricing. *See* H.R. Rep. 102-384, pt. 2, at 16. In fact, HRSA invoked that authority in its 1997 Notice, 62 Fed. Reg. at 45824, which after notice and comment resulted in a Final Notice recognizing the availability of a "rebate option for State AIDS Drug Assistance Programs (ADAPs) . . . as an optional alternate means of accessing section 340B discount pricing," 63 Fed.

[9] J&J quotes the final sentence of this passage to support its theory that PPAs are the exclusive means by which HRSA can choose not to provide for rebates. *See* J&J Opp'n at 24. As discussed above, nothing in the statute itself hamstrings the Secretary's exercise of discretion. And read in context, the Court reads this sentence as emphasizing the discretion delegated to the Secretary rather than confining that discretion to PPAs.

Reg. 35239, 35239 (June 29, 1998). At the time, "most ADAPs ha[d] drug purchasing systems that ha[d] prevented their participation in the section 340B discount program." 62 Fed. Reg. at 45824. So HRSA approved a rebate option for ADAPs, and only ADAPs. 63 Fed. Reg. at 35241–42. In response to a comment urging "that HRSA not consider any further expansion [of the rebate mechanism] to other categories of entities," HRSA responded, that "[a]t this time, we agree," and "only recognize[d] a rebate option for the State [ADAPs]." *Id.* Thus, HRSA's previous exercise of discretion to "provide" for a rebate option for particular covered entities further supports the Court's plain reading of the statute.

J&J pieces together unrelated quotes from that Final Notice to suggest the 340B statute requires the Secretary to allow for rebates. According to J&J, the Final Notice "confirmed that HRSA was not 'propos[ing] a specific mechanism for accessing [340B] rebates' in order to 'allow maximum flexibility' between the state ADAPs and manufacturers." J&J MSJ at 8–9 (quoting 63 Fed. Reg. at 35239, 35241); *see* J&J's Opp'n at 24 n.4. To the extent J&J argues that these two HRSA quotes refer to manufacturer access to rebates generally, context rebuts that suggestion. In the first quote, HRSA rejected a request that the guidelines provide for a standardized rebate process because the "Federal Register notice requested comments only on the *recognition* of a rebate option and did not propose a specific mechanism for accessing such rebates." 63 Fed. Reg. at 35239 (emphasis added). For the second quote, in response to a request that HRSA develop a "comprehensive and enforceable contract between the State ADAP program and the manufacturer" that would include specific data elements, HRSA responded that it would prefer to afford those parties "maximum flexibility" in "reaching such agreements." *Id.* at 35241. In context, neither of these quotes supports that manufacturers should be able to implement rebate models for non-ADAPs without prior approval of the Secretary. And as

Defendants aptly point out "nothing in the legislative history suggests that Congress contemplated a system where manufacturers would unilaterally decide whether to offer rebates or discounts without any role for the Secretary." Gov't Reply at 4. The Court agrees.

In sum, based on the plain and unambiguous language of the 340B statute, and supported by its purpose and history, HRSA has the authority to "provide" for discounts, rebates, or both. This conclusion defeats J&J's claim that HRSA lacked the authority to require prior approval of J&J's rebate model. *See* J&J MSJ at 31. So, the remaining issue is whether HRSA exercised its authority lawfully.

B. Legality of HRSA's Letters

J&J provides two main theories as to why HRSA's "rejection" of its rebate model was unlawful: (1) HRSA was required to conduct notice-and-comment rulemaking before rejecting J&J's rebate model, which it contends was a legislative rule; and (2) HRSA's differential treatment of covered entities' replenishment models and J&J's rebate model was arbitrary and capricious. J&J MSJ at 39–45. In J&J's final brief, it also argues that "in rejecting J&J's Rebate Model, HRSA disregarded key aspects of the problem that J&J had raised." Pl.'s Br. in Resp. to Br. of Intervenors and Reply in Supp. of Pl.'s Mot. for Summ. J. ("J&J Second Reply") at 15, ECF No. 52. None of these arguments has merit.

1. Required Procedures

Unlike legislative rules, which "have the 'force and effect of law' and may be promulgated only after public notice and comment," interpretive rules do not require those procedures under the APA. *Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 250 (D.C. Cir. 2014) (quoting *INS v. Chadha*, 462 U.S. 919, 986 n.19 (1983)); *see* 5 U.S.C. § 553(b)(A). An interpretive rule "is one that 'derive[s] a proposition from an existing document,' such as a

statute, regulation, or judicial decision, 'whose meaning compels or logically justifies the proposition.'" *Nat. Res. Def. Council v. Wheeler*, 955 F.3d 68, 83 (D.C. Cir. 2020) (alteration in original) (quoting *Cath. Health Initiatives v. Sebelius*, 617 F.3d 490, 494 (D.C. Cir. 2010)). "[I]nstead of creating legal effects," an interpretive rule "puts the public on notice of *pre-existing* legal obligations or rights." *Id.*

That is precisely what happened here. As discussed at length above, any rebate or discount must be "provided by the Secretary." 42 U.S.C. § 256b(a)(1). In correspondence with J&J, which HRSA published on its website, HRSA interpreted the 340B statute and informed J&J that because HRSA had not provided for J&J's rebate model, implementation of that model would violate the 340B statute and the PPA. *See* AR 48, 66, 202. Specifically, J&J faults HRSA for stating that "implementing a rebate proposal without Secretarial approval would violate Section 340B(a)(1)," J&J MSJ at 2, but that is a near restatement of the plain text of the statute, *see* 42 U.S.C. § 256b(a)(1). And even applying the legislative-versus-interpretive factor J&J considers "most pertinent" here, the Court has little doubt that there would be "an adequate legislative basis for [an] enforcement action," even had HRSA not sent J&J its letters reiterating that the Secretary had not provided for J&J's rebate model. J&J Opp'n at 30 (quoting *Am. Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993)).

Further, as the Agency points out, there are other sources of law to support HRSA's threat to terminate J&J's PPA. *See* Gov't Reply at 8. First, the PPA itself permits termination "for a violation of the Agreement or other good cause." *See* AR 42. And second, the Medicaid statute also permits "terminations of agreements described in section 256b(a)(1)." *See* 42 U.S.C. § 1396r-8(b)(4)(B)(v). Here, rather than announcing any new rule, HRSA merely reminded J&J that violation of its 340B obligations, such as implementation of an unapproved rebate model,

could result in termination from the 340B Program. That statement did not announce a legislative rule, so the APA did not require notice and comment.

2. Arbitrary-and-Capricious Review

Arbitrary-and-capricious review is "highly deferential" and "presumes agency action to be valid." *Am. Wildlands*, 530 F.3d at 997 (quoting *Ethyl Corp. v. EPA*, 541 F.2d 1, 34 (D.C. Cir. 1976)). As mentioned above, "an agency acts arbitrarily or capriciously if it 'has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'" *Am. Wildlands*, 530 F.3d at 997–98 (quoting *State Farm*, 463 U.S. at 43). Further, "[i]t is a fundamental principle of administrative law that agencies must treat like cases alike." *Grayscale Invs., LLC v. Sec. & Exch. Comm'n*, 82 F.4th 1239, 1242 (D.C. Cir. 2023). But "[a] necessary component of any claim that an agency acted arbitrarily and capriciously in this respect is that the differently treated entities are, in fact, 'similarly situated.'" *Vanda Pharms., Inc. v. Food & Drug Admin.*, No. 1:22-CV-01432, 2023 WL 6035663, at *14 (D.D.C. Aug. 2, 2023), *aff'd sub nom. Vanda Pharms., Inc. v. U.S. Food & Drug Admin.*, 123 F.4th 513 (D.C. Cir. 2024). J&J has articulated two theories for why HRSA's "rejection" of its rebate model was arbitrary and capricious: (1) differential treatment and (2) failure to consider an important aspect of the problem.

a. Differential Treatment

J&J argues that HRSA's "inconsistent treatment of rebate and replenishment models" constitutes arbitrary and capricious agency action. *See* J&J MSJ at 42–45. But, as HRSA explained, J&J's new rebate model and historically used replenishment models have material

differences that justify their disparate treatment. In HRSA's September 17, 2024 letter, it specifically addressed these differences:

> First, under a typical replenishment structure, a covered entity generally makes an initial purchase at a higher price, then subsequent, ongoing drug purchases are at the 340B price. By contrast, under the J&J proposal, covered entities would be forced to pay a higher price point up front for *every* purchase. This would create significantly higher up-front costs for covered entities. Second, the 340B statute explicitly limits rebate models to those that have been approved by the Secretary. Third, covered entities voluntarily choose to use replenishment processes; J&J's proposal is not voluntary for covered entities.

AR 203. This explanation for different treatment is both "reasonable and reasonably explained for purposes of the APA's deferential arbitrary-and-capricious standard." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 417 (2021).

First, HRSA emphasized that though the replenishment model requires an initial full-price purchase, it functions from that point on as a discount model. *See* AR 203. The rebate model, in contrast, requires continuous purchasing at the Wholesale Acquisition Cost. *See* J&J MSJ at 43. True, J&J asserts that covered entities will "obtain a rebate seven to ten days after submitting data supporting the 340B purchase," which it claims is shorter than many wholesaler standard payment terms. J&J MSJ at 43; J&J Opp'n at 33; AR 208–09. But this theory still does not account for the possibility that covered entities may store a drug for some time before dispensing the drug, and only then become eligible for a rebate. *See* Intervenors' Reply at 11. This possibility is supported by the record before HRSA, which contained 340B hospitals' concerns that they "will be forced to incur higher carrying costs for these drugs, essentially floating revenue to drug manufacturers" and "reduc[ing] the hospitals' resources available for other patient care." AR 568. Thus, HRSA reasonably concluded that a change from a replenishment model to a rebate model would be material. And though the Court appreciates that J&J's model also "anticipates functionality" with a capped level of rebates paid based on

purchase data only, the availability of this functionality on a wide scale would seem to defeat the stated necessity of a rebate model. *See* J&J Second Reply at 21. Broad availability of this limited exception also runs contrary to J&J's own explanation of its model for STELARA and XARELTO, which entitles covered entities to rebate "immediately upon *dispensing*." *Id.* (emphasis added). HRSA's conclusion was therefore reasonable.

Second, HRSA based its different treatment of J&J's rebate model and covered entities' replenishment models on the text of the 340B statute. AR 203. As discussed above, the 340B statute gives the Secretary discretion to "provide[]" for "any rebate or discount." 42 U.S.C. § 256b(a)(1). This includes the discretion to provide for one and not the other. Replenishment models are discount models that HRSA has provided for since at least 1996. *See* 61 Fed. Reg. at 43554. In contrast, the Court is only aware of one rebate model HRSA has approved, and that approval was limited to ADAPs. *See* 63 Fed. Reg. at 35241–42. The statutory distinction between rebate models and replenishment models supports HRSA's reasonable conclusion that they are differently situated.

Third, HRSA distinguished replenishment models based on their voluntary adoption by covered entities, unlike J&J's rebate model, to which covered entities have protested. AR 203. J&J's response to this reason is confusing: "HRSA's position thus inexplicably treats one class of program stakeholders—covered entities—more favorably than another set of stakeholders—manufacturers." J&J MSJ at 44; J&J Opp'n at 34. Of course HRSA might treat these two groups differently; covered entities are the beneficiaries of the lower prices guaranteed by the 340B Program. *See* H.R. Rep. 102-384, pt. 2, at 12 (1992) ("In giving these 'covered entities' access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive

services."). Assessing the covered entities' voluntary compliance with a pricing mechanism is an appropriate consideration that is consistent with the Program's purpose. *See* Gov't Reply at 10. And giving covered entities the ability to choose between available pricing mechanisms is consistent with past practice. For instance, when HRSA approved a rebate option for ADAPs, it rejected a commenter's request that HRSA mandate a "single mechanism" for pricing because "[i]t would be difficult to administer a rebate program in which a given State ADAP used both the discount option and the rebate option." 63 Fed. Reg. at 35240. Instead, HRSA emphasized that the "rebate option is an alternate method of accessing 340B pricing" and that while some ADAPs would use the rebate option, others would "develop systems to access a direct discount." *Id.* Allowing covered entities these choices is not a defect, but by design. This historical practice further supports HRSA's distinction based on the voluntariness of covered entities' participation in J&J's rebate model.[10]

HRSA provided multiple reasons why J&J's rebate model is different from replenishment models. Because HRSA reasonably explained key differences that justify different treatment of the models, J&J's argument that the differential treatment was arbitrary and capricious is without merit.

[10] Amicus Washington Legal Foundation suggests that HRSA should not have considered the voluntariness of J&J's rebate model because voluntariness "is irrelevant to whether a pricing mechanism complies with the 'shall offer' provision." Br. of Amicus Curiae Wash. Legal Found. at 19, ECF No. 22-2. Amicus highlights that involuntary distribution conditions were upheld in *Sanofi Aventis* and *Novartis*. *Id.* In those cases, the issue was whether manufacturers' distribution conditions violated the "shall offer" provision of 42 U.S.C. § 256b(a)(1). *Sanofi Aventis, U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 706 (3d Cir. 2023); *Novartis*, 102 F.4th at 464. Here, HRSA distinguished between J&J's rebate model and replenishment models, a different inquiry than whether the conditions J&J's rebate model would impose on covered entities are so onerous as to not constitute a bona fide offer. *See Novartis*, 102 F.4th at 464. Because HRSA was deciding a different issue, and for the reasons discussed above, its consideration of voluntariness was not in error.

b. Failure to Consider an Important Aspect of the Problem

J&J argues that "in rejecting J&J's Rebate Model, HRSA disregarded key aspects of the problem that J&J had raised, including extensive evidence of widespread noncompliance with 340B program integrity requirements," as well as "the challenges confronting J&J in adhering to its dueling obligations under the 340B program and the prescription drug provisions of the Inflation Reduction Act." J&J Second Reply at 15–16. Though J&J's earlier briefing makes only passing references to this theory, J&J articulates it explicitly for the first time in its brief in opposition to Intervenors' motion for summary judgment. *See id.* at 13–18. This is likely a result of another court's grant of summary judgment on this ground to a plaintiff in a related case, *Eli Lilly & Co. v. Kennedy*, No. 24-cv-3220 (DLF), 2025 WL 1423630, at *13–14 (D.D.C. May 15, 2025).[11]

To determine whether HRSA considered the important aspects of the problem here, it is necessary to distill what problem HRSA addressed. In its August 14, 2024 letter, HRSA stated that "implementing [a rebate] proposal at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval of a rebate model such as J&J has proposed." AR 66. HRSA's September 17, 2024 letter reiterated that position, and differentiated J&J's rebate model from replenishment models, as discussed above. AR 202–03. And HRSA's September 27, 2024 letter emphasized that, at that time and from HRSA's perspective, J&J had "not requested Secretarial approval." AR 214. This makes sense, as J&J's position in its letters to HRSA clearly stated J&J's belief that it did not need HRSA's approval to

[11] In light of the *Lilly* court's holding that HRSA's ongoing consideration of rebate models rendered the court's review premature, *see Lilly*, 2025 WL 1423630, at *13, J&J emphasizes the finality of HRSA's "rejection" of its rebate model, *see* J&J Second Reply at 13–15. "As finality is not jurisdictional under the APA," and Defendants did not raise this issue, the Court "need not decide this matter." *Vanda Pharms.*, 123 F.4th at 521.

unilaterally implement its rebate model. *See* AR 72, 191–92, 209. After this initial refusal to approve J&J's rebate model, J&J continued communicating and meeting with HRSA about its proposed rebate model, but "given the urgency of the IRA deadlines, J&J . . . file[d] this lawsuit." *See* J&J Second Reply at 15.

Defendants draw a distinction between HRSA's position regarding J&J's rebate model as of September 2024, and the permissibility of rebate models generally. *See* Gov't Reply at 13–14. The Court finds this distinction reasonable, given that J&J's Complaint challenges HRSA's letters dated August 14, September 17, and September 27. *See* Compl. ¶¶ 130–36. True, these letters did not address the problems of 340B Program integrity or pending IRA obligations for manufacturers that J&J described as motivating its proposed shift in pricing models. But that is because, even in its motion for summary judgment, J&J has focused on HRSA's "'Secretarial approval' policy" as HRSA's legal error. *See* J&J MSJ at 3, 42. Were the Agency's position that J&J's rebate model could never be implemented at all, then J&J would have a strong argument that HRSA's explanations are lacking. But because the legal question HRSA responded to in its letters was whether it had provided for rebates—which would constitute a departure from HRSA's past practice in almost all instances for the past three decades—the Court concludes that HRSA's assertion of its statutory authority can "reasonably be discerned" and is sufficiently explained. *See Xcel Energy Servs. Inc. v. FERC*, 41 F.4th 548, 557 (D.C. Cir. 2022) (quoting *State Farm*, 463 U.S. 29, 43); AR 202–03.

The Court understands that J&J faces competing constraints on its ability to participate in the 340B Program and IRA Negotiation Program while protecting the integrity of those programs. HHS has represented in other litigation that it "continues to carefully evaluate its options alongside ongoing efforts to address 340B program integrity matters and keeping in

mind the approaching effective date of certain Inflation Reduction Act requirements." Notice, *Eli Lilly & Co. v. Kennedy*, No. 24-cv-3220 (D.D.C. May 2, 2025), ECF No. 48. The Court is hopeful HHS will provide meaningful guidance soon. At the same time, the Court struggles to understand the necessity of J&J's rebate model as it relates to program integrity. J&J represents that a key benefit of its model is access to claim-level data that "covered entit[ies] already collect[] and keep[] in the normal course of business," and that with that data, J&J will be able to process rebates within ten days. AR 61. At the same time, J&J represents that it will be unable to comply with the 14-day deadline to process rebates under the IRA Negotiation Program. *See* Motion to Expedite at 4, ECF No. 19. If all J&J needs is claim-level data, it is unclear why a rebate model is necessary to obtain that data. *See Novartis*, 102 F.4th at 463 (supporting that manufacturers can require standard claims data from covered entities without violating their bona fide offer obligation). Regardless, based on the record before HRSA as of September 27, 2024, its position that implementation of a rebate model without approval would violate the 340B statute was neither contrary to law nor arbitrary and capricious. Accordingly, and for the reasons discussed above, the Court denies J&J's motion for summary judgment, and grants Defendants' and Intervenors' cross motions for summary judgment.

V. CONCLUSION

For the foregoing reasons, Plaintiff's Motion for Summary Judgment (ECF No. 18) is **DENIED**; Proposed Amici's Motions for Leave to File Amicus Briefs (ECF Nos. 21, 22, 23, 25, 28, 33, 38) are **GRANTED**; Plaintiff's Motion to Strike (ECF No. 39) is **DENIED**; and Defendants' and Intervenor-Defendants' Cross Motions for Summary Judgment (ECF Nos. 41, 54) are **GRANTED**. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: June 27, 2025

RUDOLPH CONTRERAS
United States District Judge