UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PREMIER, INC., *Plaintiff*, v. HEALTH RESOURCES AND SERVICES ADMINISTRATION, *et al.*, *Defendants*.	Civil Action No. 24 - 3116 (LLA)

MEMORANDUM OPINION

Congress has determined that certain healthcare providers are eligible to purchase prescription drugs at discounted prices, which manufacturers must offer as a condition for participation in the Medicaid program. For qualifying hospitals to access the lower prices, they may not obtain covered prescription drugs through a group purchasing organization ("GPO") or an agreement that negotiates lower prices through members' collective bargaining power. This case concerns a 2013 policy issued by the Health Resources and Services Administration ("HRSA") about how hospitals subject to that group purchasing prohibition procure and pay for covered drugs ("2013 Policy").

Plaintiff Premier, Inc., brings this action against HRSA, HRSA Administrator Thomas J. Engels, the U.S. Department of Health and Human Services ("HHS"), and HHS Secretary Robert F. Kennedy, Jr.,[1] alleging that the 2013 Policy is an impermissible legislative rule that is contrary

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[1] Premier named former HRSA Administrator Carole Johnson and former HHS Secretary Xavier Becerra as Defendants, but the current officials are "automatically substituted" as parties pursuant to Federal Rule of Civil Procedure 25(d).

to the statute and arbitrary and capricious in violation of the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 *et seq.* ECF No. 1. Premier asks the court to declare the 2013 Policy unlawful and set it aside. *Id.* at 33-34. Both parties have moved for summary judgment. ECF Nos. 11, 15. For the reasons discussed below, the court concludes that the 2013 Policy is arbitrary and capricious and must be vacated. Accordingly, the court will grant Premier's motion in part and deny Defendants' motion.

I. STATUTORY BACKGROUND AND REGULATORY HISTORY

A. Section 340B Program

"Section 340B of the Public Health Services Act . . . imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113 (2011). "The ceiling price is fixed by a statutory formula strikingly generous to purchasers." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 456 (D.C. Cir. 2024). HRSA, a unit within HHS, administers the program, *Astra USA*, 563 U.S. at 113, which Congress established in the Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71.[2] To incentivize companies to provide discounts, the law conditions a drug manufacturer's "eligibility for Medicaid matching funds" and Medicare Part B payments on the manufacturer's participation in the Section 340B Program. *Cares Cmty. Health v. U.S. Dep't of Health & Hum. Servs.*, 944 F.3d 950, 955 (D.C. Cir. 2019) (quoting *Univ. Med. Ctr. of S. Nev. v. Shalala*, 173 F.3d 438, 439 (D.C. Cir. 1999)); 42 U.S.C. § 1396r-8(a)(1), (a)(5).

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[2] The Veterans Health Care Act of 1992 amended the Public Health Service Act, Pub. L. No. 78-410, ch. 373, 58 Stat. 682 (1944). *See* § 602(a), 106 Stat. at 4967.

Participating manufacturers enter into agreements with HRSA to charge "covered entities" less than "predetermined ceiling prices" derived from the "'average' [manufacturer] . . . prices and rebates calculated under the Medicaid Drug Rebate Program." *Astra USA*, 563 U.S. at 115 (quoting 42 U.S.C. § 256b(a)(1)). The Medicaid Drug Rebate Program, enacted in 1990, "covers a significant portion of drug purchases in the United States" and served as a template for the Section 340B Program. *Id.* at 114.

To qualify as a "covered entity," a facility must "fit within [the] narrow categories" of "healthcare providers" set forth in 42 U.S.C. § 256b(a)(4), which Congress expanded in the Affordable Care Act in 2010. *Novartis Pharms.*, 102 F.4th at 455-56; *see* Pub. L. No. 111-148, §§ 7101-02, 124 Stat. 119, 821-27. Only one type of covered entity is implicated here: hospitals (1) that are run by a state or local government or certain public or private non-profits or that "provide health care services to low income individuals" who are not Medicare beneficiaries; (2) that have a "disproportionate share adjustment percentage" above the statutory threshold;[3] and (3) that "do[] not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement." 42 U.S.C. § 256b(a)(4)(L). The court refers to these covered entities as disproportionate share hospitals ("DSHs"). *See, e.g.*, *Pharm. Rsch. & Mfrs. of Am. v. U.S. Dep't of Health & Hum. Servs.*, 43 F. Supp. 3d 28, 31 (D.D.C. 2014).

The parties' dispute concerns the third eligibility requirement, known as the "GPO prohibition," which bars DSHs from obtaining "covered outpatient drugs through a group

[3] The "disproportionate share adjustment percentage" is a complex formula used to identify "hospitals serving an 'unusually high percentage of low-income patients'" that are entitled to "enhanced Medicare payments" for services provided to certain Medicare beneficiaries. *Becerra v. Empire Health Found., for Valley Hosp. Med. Ctr.*, 597 U.S. 424, 429 (2022) (quoting *Sebelius v. Auburn Reg'l Med. Ctr.*, 568 U.S. 145, 150 (2013)).

purchasing organization or other group purchasing arrangement." 42 U.S.C. § 256b(a)(4)(L)(iii). A "covered outpatient drug" for Section 340B purposes is any drug that meets the definition of that term in Section 1927(k) of the Social Security Act, with several exceptions not at issue here. *Id.* § 256b(b)(1), (b)(2).

In addition to meeting the statutory criteria for the Section 340B Program, covered entities must comply with program requirements set forth in 42 U.S.C. § 256b(a)(5). "[T]he statute prohibits 'diversion,' which occurs when covered entities 'resell or otherwise transfer the drug to a person who is not a patient of the entity.'" *Novartis Pharms.*, 102 F.4th at 456 (quoting 42 U.S.C. § 256b(a)(5)(B)). It also "prohibits covered entities from receiving the [S]ection 340B discount on drugs also subject to a Medicaid rebate." *Id.*; *see* 42 U.S.C. § 256b(a)(5)(A)(i). And a covered entity "shall permit the [HHS] Secretary and the manufacturer of a covered outpatient drug" to "audit at the Secretary's or the manufacturer's expense" any of the entity's "records . . . that directly pertain" to its "compliance" with the prohibitions on diversion and duplicating discounts. 42 U.S.C. § 256b(a)(5)(C).

Since Congress created the Section 340B Program in 1992, "[t]he mechanism for distributing covered drugs . . . has evolved." *Novartis Pharms.*, 102 F.4th at 457. One popular mechanism is the source of the parties' dispute. The D.C. Circuit has described at a high level how it works:

> While some contract pharmacies maintain separate inventories of [S]ection 340B drugs, most fill prescriptions from inventories that intermingle discounted and non-discounted drugs. Only after dispensing the drugs do these pharmacies attempt to discern whether individual customers were patients of covered entities—in other words, whether individual prescriptions were eligible for the discount. Many pharmacies outsource this determination to third-party administrators . . . . Once the pharmacy or the administrator categorizes a certain number of prescriptions as

> eligible, the pharmacy places an order to replenish its [S]ection 340B purchases.

Id. Both parties describe this as a "replenishment model" or a "virtual inventory model." *See* ECF No. 11-1, at 29; ECF No. 15-1, at 5; *see also* ECF No. 22-1, at 87-88.[4]

B. Regulatory History

The HHS Secretary lacks general rulemaking authority over the Section 340B program. *Novartis Pharms.*, 102 F.4th at 456; *see* 42 U.S.C. § 256b(d)(1)(B)(i)(I) (allowing the Secretary to "[d]evelop[] and publish[] through an appropriate policy or regulatory issuance" the "standards and methodology for the calculation of ceiling prices"); 42 U.S.C. § 256b(d)(1)(B)(vi)(I) (granting the Secretary authority to impose sanctions that "shall be assessed according to standards established in regulations to be promulgated by the Secretary"); 42 U.S.C. § 256b(d)(3)(A) (directing the Secretary to "promulgate regulations to establish and implement an administrative process for the resolution of claims" filed by covered entities and manufacturers); *see also Pharm. Rsch. & Mfrs. of Am.*, 43 F. Supp. 3d at 41 (describing these three areas as ones where "Congress specifically authorized rulemaking"). "Nonetheless, [HRSA] has issued guidance documents interpreting and implementing the scheme." *Novartis Pharms.*, 102 F.4th at 456. Among those, HRSA's 1994 and 2013 guidance documents are relevant here.

After Section 340B's enactment, "HHS initially interpreted the [GPO prohibition] as barring only 'double dipping'—that is, hospitals could participate in both the [S]ection 340B discount program and a group purchasing organization provided that the hospital did not receive 340B discounts on the same drugs purchased through the group purchasing organization." *Univ.*

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[4] For consistency, the court refers to it as the "replenishment model."

Med. Ctr. of S. Nev., 173 F.3d at 439. In December 1993, HRSA announced proposed guidelines and invited public comment. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 58 Fed. Reg. 68922 (Dec. 29, 1993) ("1993 Proposed Policy"). That notice advanced a "new policy approach" with respect to "the group purchasing restriction" for disproportionate share hospitals: "[i]f a DSH participates in a [GPO] or arrangement for covered outpatient drugs, the DSH will no longer be an eligible covered entity and cannot purchase covered outpatient drugs at the [S]ection 340B discount prices." *Id.* at 68924. HRSA determined that "[t]he proposed policy would appear to achieve the Congressional intent better than [the agency's] earlier interpretation" and prevent "Federal dollars [from] being lost."[5] *Id.*

In May 1994, HRSA issued a final notice with its revised guidance. Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25110 (May 13, 1994) ("1994 Policy"). As it had in the proposed notice, HRSA concluded in the 1994 Policy "that participation in a group purchasing organization for the purchase of covered outpatient drugs would . . . render the hospital ineligible for 340B discounts." *Univ. Med. Ctr. of S. Nev.*, 173 F.3d at 439; *see* 1994 Policy, 59 Fed. Reg. at 25113 (adopting the same language as the proposed policy). At the same time, HRSA left undisturbed a DSH's ability to use GPOs for inpatient drugs and any outpatient drugs not subject to Section 340B. *See generally* 1994 Policy, 59 Fed. Reg. 25110. And, in response to an inquiry whether Section 340B "require[d] separate

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[5] As HRSA explained it, when a DSH participated in both a GPO and the Section 340B Program, the hospital would give its Medicaid provider number to the state Medicaid agency so the agency could "exclude [the hospital] from the Medicaid rebate mechanism" and the hospital could avoid the statutory prohibition on receiving both a Medicaid discount and a Section 340B discount on the same drug. 1993 Proposed Policy, 58 Fed. Reg. at 68924; *see* 42 U.S.C. § 256b(a)(5)(A)(i). GPO drugs were thereby "excluded from [the Medicaid] rebate mechanism" and the federal Medicaid program would "los[e] the statutory rebate it would otherwise receive." 1993 Proposed Policy, 58 Fed. Reg. at 68924.

inventories [for prescription drugs]" to avoid drug diversion, which the commenter suggested "would place a hardship on most hospitals," HRSA confirmed in the 1994 Policy that "[t]here is no requirement for separate inventories." *Id.* at 25111.

HRSA issued updated guidance in 1996, 2009, and 2010, but the next relevant change came in 2013. Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549 (Aug. 23, 1996); Notice Regarding 340B Drug Pricing Program—Children's Hospitals, 74 Fed. Reg. 45206 (Sep. 1, 2009) ("2009 Policy"); Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (Mar. 5, 2010). In February 2013, HRSA's Office of Pharmacy Affairs ("OPA") issued a "program notice" concerning the Section 340B Program's "policy regarding the statutory prohibition against obtaining covered outpatient drugs through a [GPO] for certain covered entities." HRSA Healthcare Sys. Bureau, Off. of Pharm. Affs., Statutory Prohibition on Group Purchasing Organization Participation, Release No. 2013-1, at 1 (Feb. 7, 2013) ("2013 Policy");[6] *see* ECF No. 22-1, at 86-88. HRSA did not issue the 2013 Policy through notice and comment, as it had done with the 1994, 2009, and 2010 policy documents. In the "Background" section of the 2013 Policy, HRSA explains that "[s]ince the beginning of the 340B Program, [the agency] has addressed violations" of the prohibition on covered entities' "'obtain[ing] covered outpatient drugs through a [GPO]'" by publishing guidance in the Federal Register. ECF No. 22-1, at 86 (quoting 42 U.S.C. § 256b(a)(4)(L)(iii)). HRSA then points to the 1994 and 2009 policy documents and states that the 2013 Policy will "further explain and clarify [its] position on questions that have arisen as the marketplace has changed." *Id.*

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[6] *Available at* https://perma.cc/CG62-PWG2.

In the next section, titled "Scope of GPO Prohibition and Certification of Compliance," HRSA explains that "[c]ompliance with the GPO prohibition is an eligibility requirement" for the Section 340B Program, and covered entities "must sign an acknowledgement of this statutory requirement" upon "registration for the 340B Program" and "attest to compliance . . . during the 340B annual recertification process." *Id.* HRSA then asserts that it is the agency's "longstanding position that a covered entity enrolled in the 340B Program subject to the GPO prohibition . . . may not use a GPO for covered outpatient drugs *at any point in time*." *Id.* at 86-87 (emphasis added). HRSA explains that, under this "longstanding position," any "hospital subject to the GPO prohibition may not purchase covered outpatient drugs through a GPO for any of its clinics/departments within the four walls of the hospital (same physical address) under any circumstance." *Id.* at 87. Instead, only "certain off-site outpatient facilities of the hospital may use a GPO for covered outpatient drugs" if those facilities meet specific criteria—including that they "[a]re not registered on the OPA 340B database as participating in the 340B Program." *Id.*

Finally—in two short paragraphs most applicable to this case—HRSA addresses the replenishment model. The agency explains that "[t]hrough HRSA's 340B Program integrity initiatives," it had become "aware that some hospitals subject to the GPO prohibition" were "purchasing covered outpatient drugs through a GPO and subsequently either (1) 'replenishing' through accounting by 'replacing' the GPO purchased drug with a drug purchased under 340B; or (2) otherwise reclassifying the method of purchase after dispensing." *Id.* In the 2013 Policy, HRSA clarified that "[t]he GPO prohibition is violated upon use of a GPO to obtain covered outpatient drugs and cannot be fixed or cured by subsequently changing the characterization through accounting or other methods." *Id.* at 87-88.

As for compliance and any sanctions for failing to follow the 2013 Policy, HRSA explains that a covered entity must comply with the GPO prohibition "before the first day [it] is eligible to purchase 340B drugs and listed on the OPA 340B database." *Id.* at 87. The agency cautioned that covered hospitals using the replenishment model "should immediately cease this practice or be found in violation of the GPO prohibition" and that any hospital found to be violating the GPO prohibition "will be removed from the 340B Program as it will no longer be eligible for participation." *Id.* at 88. HRSA concludes the 2013 Policy by reiterating that "the GPO prohibition is an eligibility requirement" and stating that hospitals "found in violation will be considered ineligible" and could potentially be "subject to repayment to manufacturers for the time period for which the violation occurred." *Id.*

II. FACTUAL BACKGROUND AND PROCEDURAL HISTORY

Premier brands itself as a "technology-driven healthcare improvement company" that "provid[es] solutions to two-thirds of all healthcare providers" in the United States. Premier, *About Premier*.[7] One of the "healthcare supply chain" solutions it offers to its clients—which include "hospitals, health systems, and other providers"—is access to a GPO program. ECF No. 22-1, at 194-95. In July 2023, Premier submitted a letter to HRSA informing the agency that it "intend[ed] to promote and to offer to its 340B hospital covered entity clients the ability to make initial purchases of drugs through their [GPO] accounts." *Id.* at 194. It acknowledged that its request would "require HRSA to either exempt [it] and its hospital clients from [the 2013 Policy] or otherwise review and reverse that analysis." *Id.* Premier therefore asked HRSA to confirm that the company's "arrangement"—"offering its 340B hospital clients lower negotiated rates for drugs

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[7] *Available at* https://perma.cc/VG32-RHF7.

to stock their initial inventories"—was lawful. *Id.* at 195. HRSA responded in December 2023 that it "d[id] not plan to exempt Premier's proposed arrangement or reverse its 2013 Policy." ECF No. 11-16.

In November 2024, Premier filed this action against HRSA, its Administrator, HHS, and its Secretary alleging that (1) the 2013 Policy is "not in accordance with law" in violation of APA Section 706(2)(C), ECF No. 1 ¶¶ 127-130; (2) the 2013 Policy is "arbitrary and capricious" in violation of APA Section 706(2)(A), *id.* ¶¶ 131-136; (3) HRSA enacted its policy "in excess of [its] statutory authority" in violation of APA Section 705(2)(C), *id.* ¶¶ 137-143; and (4) the 2013 Policy is unlawful under the Declaratory Judgment Act, 28 U.S.C. § 2201(a), *id.* ¶¶ 144-147. Premier asks the court to vacate HRSA's "decision denying [the] request for an exemption from the 2013 Policy," "[e]njoin HRSA from applying the 2013 Policy to Premier or any of Premier's covered entity hospital members," "[d]eclare that the purchasing of initial neutral inventory in a virtual replenishment system through a GPO . . . is lawful," "[d]eclare that [the] 2013 Policy is unlawful [as] applied to Premier and its members," vacate the 2013 Policy in its entirety, and award Premier costs and fees. *Id.* at 33-34. The parties have moved for summary judgment and both motions are fully briefed. ECF Nos. 11, 15, 17, 21.

III. LEGAL STANDARDS

To resolve summary judgment motions on APA review, the court does not apply the ordinary framework from Federal Rule of Civil Procedure 56; instead, "[t]he 'entire case' . . . is a question of law." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001) (quoting *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993)). "Summary judgment thus serves as the mechanism for deciding . . . whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review."

Alabama v. U.S. Army Corps of Eng'rs, 774 F. Supp. 3d 142, 153 (D.D.C. 2025) (alteration in original) (quoting *Albino v. United States*, 78 F. Supp. 3d 148, 163 (D.D.C. 2015)).

The APA requires the court to "hold unlawful and set aside" any "agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "In determining whether an agency's interpretation of its governing statute is contrary to law," the court exercises its "'independent judgment' and 'appl[ies] all relevant interpretive tools' to reach 'the best reading of the statute.'" *Env't Def. Fund v. U.S. Env't Prot. Agency*, 124 F.4th 1, 11 (D.C. Cir. 2024) (quoting *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 394, 400 (2024)).

Agency action that is "not contrary to law" must still "be 'reasonable and reasonably explained,'" or else it is arbitrary and capricious. *Id.* (quoting *Fed. Commc'ns Comm'n v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021)). An agency violates the APA if it "has relied on factors which Congress has not intended it to consider," "entirely failed to consider an important aspect of the problem," or "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." *Solondz v. Fed. Aviation Admin.*, 141 F.4th 268, 276 (D.C. Cir. 2025) (quoting *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). It is also arbitrary and capricious for an agency to "ignore[] the reasonable reliance interests of regulated parties." *Affirmed Energy, LLC v. Fed. Energy Regul. Comm'n*, 166 F.4th 1070, 1079 (D.C. Cir. 2026). In conducting arbitrary-and-capricious review, the court "may not substitute [its] judgment for that of the Secretary," *Dep't of Com. v. New York*, 588 U.S. 752, 773 (2019), and it "may only uphold a rule 'on the basis articulated by the agency'

in the rule making record," *Genuine Parts Co. v. Env't Prot. Agency*, 890 F.3d 304, 314 (D.C. Cir. 2018) (quoting *State Farm*, 463 U.S. at 50).

IV. DISCUSSION

The parties dispute three issues: (1) whether the 2013 Policy is a legislative rule that HRSA lacked authority to promulgate; (2) whether the 2013 Policy is contrary to the GPO prohibition in Section 340B, 42 U.S.C. § 256b(a)(4)(L)(iii); and (3) whether the 2013 Policy, and HRSA's subsequent decision not to grant Premier an exemption from that policy, is arbitrary and capricious in violation of the APA. The court agrees with Premier that the 2013 Policy is arbitrary and capricious and must be set aside; accordingly, the court will grant Premier's motion for summary judgment as to that challenge. In light of that conclusion, the court determines that it need not decide whether the 2013 Policy is a legislative rule, whether the 2013 Policy conflicts with Section 340B, or whether HRSA's denial of Premier's exemption request was arbitrary and capricious.

A. The 2013 Policy Is Arbitrary and Capricious

Arbitrary-and-capricious review is "deferential, and a court may not substitute its own policy judgment for that of the agency." *Inteliquent, Inc. v. Fed. Commc'ns Comm'n*, 35 F.4th 797, 802 (D.C. Cir. 2022) (quoting *Prometheus Radio Project*, 592 U.S. at 423). It must only "ensure[] that the agency has acted within a zone of reasonableness" by "consider[ing] the relevant issues and reasonably explain[ing] the decision." *Prometheus Radio Project*, 592 U.S. at 423. Even when the agency's decision is "of less than ideal clarity," the court will still uphold it if "the agency's path may reasonably be discerned." *Epsilon Elecs., Inc. v. U.S. Dep't of Treasury, Off.*

of Foreign Assets Control, 857 F.3d 913, 928 (D.C. Cir. 2017) (quoting *State Farm*, 463 U.S. at 43).

Premier contends that the 2013 Policy is arbitrary and capricious because it "directly frustrates" the clear purpose of Section 340B, ECF No. 11-1, at 25-26; ECF No. 17, at 22-24; contradicts the so-called "prudent buyer principle," according to which healthcare providers should be prudent and cost-conscious market participants, ECF No. 11-1, at 26-27; and fails to justify its conclusion while also marking an unreasoned and unexplained departure from HRSA's prior understanding of Section 340B, ECF No. 11-1, at 28-30; ECF No. 17, at 25-27. Defendants primarily contest Premier's characterization of Section 340B's legislative purpose, the application of the prudent-buyer principle, and HRSA's prior practice and interpretation, ECF No. 15-1, at 15-19; ECF No. 21, at 11-12, but Defendants also assert that the 2013 Policy cannot be arbitrary or capricious because it is the only permissible interpretation of Section 340B, ECF No. 15-1, at 14-15; ECF No. 21, at 9-10. The court concludes that the 2013 Policy is arbitrary and capricious.[8]

HRSA offers almost no reasoning in the 2013 Policy—and the little it does provide fails to explain why the agency reached the conclusion it did. "A 'fundamental' requirement of administrative law is that an agency 'set forth its reasons' for decision; an agency's failure to do so constitutes arbitrary and capricious agency action." *Tourus Records, Inc. v. Drug Enf't Admin.*, 259 F.3d 731, 737 (D.C. Cir. 2001) (quoting *Roelofs v. Sec'y of Air Force*, 628 F.2d 594, 599

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[8] Premier also maintains that HRSA denied its exemption request without any explanation, which is arbitrary and capricious independent of any defects in the 2013 Policy, ECF No. 11-1, at 30-31; ECF No. 17, at 28-30, and Defendants argue that the cursory denial was warranted because the agency's justification was "self-explanatory," ECF No. 15-1, at 19; *see* ECF No. 21, at 11. Given the court's conclusion that the 2013 Policy is arbitrary and capricious, Premier's challenge to the specific exemption denial is moot.

(D.C. Cir. 1980)). HRSA's justification for construing the GPO prohibition to apply to the replenishment model is the unexplained and unreasoned conclusion that Section 340B and the agency's prior policies both compel that result. But HRSA's suggestion that the model violates Section 340B is devoid of any discernible reasoning and the agency's scant discussion of its own prior policies is non-responsive to the interpretive question posed by use of the replenishment model.[9]

The following three statements are the closest that HRSA gets in the 2013 Policy to interpreting Section 340B or the agency's prior guidance: (1) "[t]he GPO prohibition is violated upon use of a GPO to obtain covered outpatient drugs and cannot be fixed or cured by subsequently changing the characterization through accounting or other methods," ECF No. 22-1, at 87-88; (2) "[i]t is HRSA's longstanding position that a covered entity enrolled in the 340B Program subject to the GPO prohibition . . . may not use a GPO for covered outpatient drugs at any point in time," *id.* at 86-87; and (3) "HRSA has not authorized th[e] GPO replenishment model," *id.* at 87. None satisfies the APA's demand for reasoned decisionmaking.

HRSA's first justification—that the GPO prohibition is violated "upon use of a GPO to obtain covered outpatient drugs and cannot be fixed or cured" with the replenishment model, *id.* at 88—does not comply with the APA. As the court understands it, HRSA is implying that Section 340B itself prohibits the replenishment model. But the statute does not *explicitly* address the replenishment model. *See* 42 U.S.C. § 256b(a)(4)(L)(iii) (prohibiting certain covered entities from "obtain[ing] covered outpatient drugs through a [GPO]"). HRSA thus had an obligation to complete "the critical step [of] connecting the facts to the conclusion." *Dickson v. Sec'y of Def.*,

[9] Because the court concludes that the 2013 Policy is arbitrary and capricious on these grounds, it need not resolve Premier's arguments about legislative purpose or the prudent-buyer principle.

68 F.3d 1396, 1405 (D.C. Cir. 1995). Defendants may be correct that Section 340B prohibits the model that Premier was using before HRSA issued the 2013 Policy, but the APA requires HRSA to explain why that is. Does the agency's understanding of the statute follow from the plain meaning of the words "obtain" or "through"? 42 U.S.C. § 256b(a)(4)(L)(iii). Does it come from the agency's interpretation of "group purchasing organization" or "group purchasing arrangement," neither of which the statute defines? *Id.* Or is it something inherent in the definition of "covered outpatient drug"? *Id.*; *see* 42 U.S.C. § 1396r-8(k)(2). Is the replenishment model invalid because of the way the GPO prohibition operates within Section 340B as a whole? *See Crowley Gov't Servs., Inc. v. Gen. Servs. Admin.*, 143 F.4th 518, 533 (D.C. Cir. 2025) (explaining the court's "duty to construe statutes, not isolated provisions" (quoting *Turkiye Halk Bankasi A.S. v. United States*, 598 U.S. 264, 275 (2023))). Or does the model rely on a statutory construction that would create superfluity or violate some other interpretive principle? *See* ECF No. 15-1, at 9 (arguing that a statute "cannot be held to destroy itself" (quoting *Citizens Bank of Md. v. Strumpf*, 516 U.S. 16, 20 (1995))).

Defendants insist that Premier's interpretation of Section 340B as permitting the replenishment model results from "a dizzying display of circular thinking," ECF No. 21, at 7, but the court's task on arbitrary-and-capricious review is to evaluate whether the *agency* "clarify[ing] [its] policy regarding the statutory [GPO] prohibition" has adequately explained its interpretation, ECF No. 22-1, at 86; *see BP Energy Co. v. Fed. Energy Regul. Comm'n*, 828 F.3d 959, 967 (D.C. Cir. 2016) (remanding an agency's order for further explanation because, on arbitrary-and-capricious review, the court determined that the agency had "failed to provide an adequate explanation of its interpretation"). At best, HRSA's invocation of Section 340B in the 2013 Policy is a restatement of the statutory text paired with a conclusion about the fate of the

replenishment model under the statute. *See* ECF No. 22-1, at 87-88 (stating that the GPO prohibition is "violated upon use of a GPO to obtain covered outpatient drugs" and concluding that entities "cannot . . . fix[] or cure[]" the violation using "accounting or other methods"); 42 U.S.C. § 256b(a)(4)(L)(iii) (prohibiting certain covered entities from "obtain[ing] covered outpatient drugs through a [GPO]"). "When an agency merely parrots the language of a statute without providing an account of how it reached its results, it has not adequately explained the basis for its decision." *Dickson*, 68 F.3d at 1405.

The second "explanation" offered by HRSA—that its "longstanding position" prohibits using a GPO to purchase covered outpatient drugs "at any point in time," ECF No. 22-1, at 86-87—does not justify the agency's conclusion that the replenishment model violates prior agency policy. Although HRSA does not specify which prior policies prove its point, the court assumes the agency is referring to those cited in the background section of the 2013 Policy. There, HRSA quoted the 1994 Policy for the proposition that when a covered entity participates in a GPO, it "cannot purchase covered outpatient drugs at the [S]ection 340B discount prices." *Id.* at 86 (quoting 1994 Policy, 59 Fed. Reg. at 25113). But this portion of the 1994 Policy simply parrots the text of Section 340B. *See* 42 U.S.C. § 256b(a)(4)(L)(iii) (prohibiting certain covered entities from "obtain[ing] covered outpatient drugs through a [GPO]"). HRSA also quotes its 2009 Policy for children's hospitals, in which it explained that those entities must certify that, as of the time they are listed in the Section 340B Program database, they "will not participate in a [GPO] for covered outpatient drugs." ECF No. 22-1, at 86 (quoting 2009 Policy, 74 Fed. Reg. at 45210). This reference does not satisfy HRSA's obligation to explain its decision to prohibit the replenishment model for entities subject to the GPO prohibition. Pointing to the certification requirement only

bears on the question whether the replenishment model is permissible if the replenishment model violates the GPO prohibition, which is the very issue the 2013 Policy purports to decide.

The only longstanding policy that can be distilled from these guidance documents is one that prohibits certain covered entities from using GPOs to obtain *covered* outpatient drugs, which makes sense because that is exactly what 42 U.S.C. § 256b(a)(4)(L)(iii) requires. But neither the 1994 Policy nor the 2009 Policy explicitly addresses the replenishment model or discusses the point at which prescription drugs become "covered outpatient drugs" in a virtual inventory system, *see generally* 1994 Policy, 59 Fed. Reg. at 25110-25114; 2009 Policy, 74 Fed. Reg. at 45206-45211, so it was incumbent on HRSA to state its reasons for why those guidance documents foreclose the practice. Absent further explanation from the agency, HRSA's characterization of its prior guidance in the 2013 Policy betrays a misunderstanding of the interpretive issue at hand because both the 1994 and 2009 guidance documents are, at least on their face, non-responsive to the question posed by covered entities' use of a GPO for drugs in a neutral inventory. Premier contends that the replenishment model *complies* with the GPO prohibition because drugs purchased for neutral inventory are not "covered outpatient drugs" under 42 U.S.C. § 256b(b)(2) and 42 U.S.C. § 1396r-8(k)(2). *See* ECF No. 11-1, at 20-22 (arguing that the "status as a covered outpatient drug depends on the circumstances in which . . . the drug is dispensed," which entities using a replenishment model do not know when they purchase neutral inventory); ECF No. 22-1, at 196 (asserting in its exemption request that, under the replenishment model, a "drug cannot be categorized as a covered outpatient drug because the recipient of the drug is undetermined"). For HRSA to rely on its prior guidance documents, it must explain the connection between the earlier, generic recitations of the statutory requirement and the application of those principles to the replenishment model. *Dickson*, 68 F.3d at 1405 (holding that the agency "omitted

the critical step—connecting the facts to the conclusion"); *cf. Select Specialty Hosp.-Bloomington, Inc. v. Burwell*, 757 F.3d 308, 312 (D.C. Cir. 2014) (explaining that, despite identifying the "guiding principles motivating" a decision, the agency's explanation was arbitrary and capricious because it was so ambiguous that it "'fail[ed] to state its reasoning'" (quoting *Checkosky v. Sec. & Exch. Comm'n*, 23 F.3d 452, 463 (D.C. Cir. 1994) (opinion of Silberman, J.))). Put differently, explaining why the mechanics of the replenishment model run afoul of the GPO prohibition was a necessary component of reasoned analysis in a document that Defendants contend embodied "the interpretation that [HRSA] has maintained since 1994." ECF No. 15-1, at 18.

Not only does HRSA fail in the 2013 Policy to meaningfully connect its earlier guidance to the replenishment model, the agency also curiously fails to address what appears (on this administrative record) to have been its pre-2013 policy of *permitting* the replenishment model.[10] "Agencies are free to change their existing policies as long as they provide a reasoned explanation for the change, display awareness that [they are] changing position, and consider serious reliance interests." *Food & Drug Admin. v. Wages & White Lion Invs., L.L.C.*, 604 U.S. 542, 568 (2025) (alteration in original) (internal quotation marks omitted). Three observations are central to this dispute. First, as Premier explains, prohibiting the replenishment model for DSHs means that these entities may have to maintain separate inventories for covered outpatient drugs and other

[10] Premier frames this argument—that the 2013 Policy marks HRSA's unreasoned departure from prior agency policy—as an independent ground for setting aside the 2013 Policy as arbitrary and capricious under the APA. *See* ECF No. 11-1, at 28-30; ECF No. 17, at 26-27. That may well be true, but as the court sees it, understanding HRSA's pre-2013 policy about DSHs using a replenishment model is essential to determining whether the agency's explanation about its "longstanding position," ECF No. 22-1, at 86, withstands scrutiny. Accordingly, while the court declines to resolve the independent basis for holding that the 2013 Policy violates the APA, the court draws on the parties' arguments to resolve Premier's arbitrary-and-capricious challenge to the policy's rationale. *See* ECF No. 17, at 25-27.

prescription drugs. ECF No. 11-1, at 11; *see* ECF No. 15-1, at 10 (conceding that separate inventories are one way to comply with the GPO prohibition). Yet as early as 1994, HRSA advised that "[t]here is no requirement for separate inventories" to avoid drug diversion. 1994 Policy, 59 Fed. Reg. at 25111. Second, it appears that prior to the 2013 Policy, HRSA allowed covered entities to use backend accounting procedures to ensure compliance with the GPO prohibition. *See* ECF No. 22-1, at 212 (explaining in OPA's frequently asked questions for DSHs that "[m]anual or *electronic* processes can be implemented to appropriately address the 340B requirements for *mixed patient care settings*," including "split billing *software*," which "may enable the covered entity *to maintain a single inventory of product for the mixed patient care settings* while ensuring compliance" (emphases added)); *see also id.* at 213 (explaining that a DSH that "cannot track utilization of 340B-priced drugs on a drug-by-drug basis" may "rely on alternative tracking systems" if OPA approves the DSH's "written request . . . describing the proposed methodology"). Third, the administrative record suggests that HRSA's own prime vendor, Apexus, acknowledged in November 2012 that "most hospitals utilize virtual inventory management software to maintain a single inventory of drugs for its inpatient and 340B/outpatient business," which involved "purchas[ing] GPO inpatient product initially" and "replenish[ing]" that inventory with Section 340B-priced drugs. *Id.* at 151 & n.24.

The administrative record is not clear enough for the court to reach a definitive conclusion regarding HRSA's pre-2013 practice around DSHs' use of GPOs for virtual inventory or, more broadly, DSHs' use of replenishment models.[11] At a minimum, however, the record—including

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[11] Premier makes a fourth argument—that a declaration from an HRSA official "acknowledged that the virtual inventory model is compliant with the 340B statute," ECF No. 11-1, at 6; *see* ECF

(*continued on next page*)

HRSA's own prior statements—could be taken as tacitly endorsing the replenishment model and possibly even permitting the conduct prohibited by the 2013 Policy. Yet the 2013 Policy offers no acknowledgement of these wrinkles—or the sea change HRSA was bringing to covered entities subject to the GPO prohibition. *See id.* at 126 (explaining that for Premier's member hospitals, the costs of complying with the 2013 Policy "range anywhere from $500,000 to $1.6 million" per hospital and that "virtually all of America's 5,000+ hospitals" use GPOs as "sourcing and purchasing partners"); *id.* at 240, 280 (340B Health, an organization that "represents over 1,100 hospitals that participate in the 340B program," explaining to HRSA's OPA director that "about 90 percent of respondents [to a 340B Health survey] that were subject to the GPO prohibition and were participating in 340B when HRSA issued the [2013] GPO policy release reported increased spending in their non-340B accounts due to HRSA's policy"). HRSA was required to explain why it thought the replenishment model was distinct from other acceptable inventory systems, why its earlier practices were distinguishable from what the 2013 Policy prohibited, and, to the extent the longstanding practice was *contrary* to the new policy, why the agency was making a change.

Finally, HRSA's third justification—that it had not authorized the replenishment model, *id.* at 87—is either unreasoned or irrelevant. To the extent HRSA is suggesting in this portion of the 2013 Policy that using the replenishment model contradicts prior agency guidance, the policy is unreasoned for the reasons the court provided in response to the agency's second "explanation." And to the extent HRSA is instead suggesting that Premier or any covered entity needs explicit

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No. 11-9—but in its exemption request, Premier conceded that the "statements were made in [a different context]" that is "not identical to the virtual replenishment models used in hospital pharmacies and do not involve the purchase of any drugs by hospitals through GPO accounts," ECF No. 22-1, at 199 & n.15. In any event, it is unclear whether the declaration is describing the model as a factual matter or expressing HRSA's approval of the practice.

agency authorization before adopting a replenishment model, that cannot be correct given that HRSA lacks rulemaking authority over much of the Section 340B Program. *See Novartis Pharms.*, 102 F.4th at 456 ("The Secretary lacks rulemaking authority over the [S]ection 340B program."); *see supra* Section I.B. Defendants have not pointed to a provision in Section 340B authorizing HRSA to require preapproval before a covered entity adopts a replenishment model.

At bottom, HRSA's "explanations" imply that the agency believes Section 340B and its prior guidance foreclose covered entities subject to 42 U.S.C. § 256(a)(4)(L)(iii) from using the replenishment model. But while HRSA cites the statutory language of the GPO prohibition and the 1994 and 2009 guidance documents, ECF No. 22-1, at 86, its conclusory justifications do not explain *why* the statute or the prior guidance documents led the agency to the ultimate determination offered in the 2013 Policy. HRSA must "point to some evidence in the record that reasonably supports where it chose to draw the line" with respect to the GPO prohibition's application to the replenishment model. *AARP v. U.S. Equal Emp. Opportunity Comm'n*, 267 F. Supp. 3d 14, 34 (D.D.C. 2017). That remains true even when the relevant choice is HRSA's interpretation of Section 340B or its prior notices. *See BP Energy Co.*, 828 F.3d at 968 (explaining that "[e]ven under the most deferential standard," an agency must engage in reasoned statutory interpretation); *cf. Council for Urological Interests v. Burwell*, 790 F.3d 212, 223 (D.C. Cir. 2015) (reviewing whether an agency's interpretation was reasonable and concluding that the agency's explanation was "plainly not a reasonable attempt to grapple with the [legislative history and] belong[ed] instead to the cross-your-fingers-and-hope-it-goes-away school of statutory interpretation").

Accordingly, the 2013 Policy is arbitrary and capricious. Under the APA, arbitrary or capricious agency action must be set aside. 5 U.S.C. § 706(2)(A). And Defendants have not

argued that vacatur—the "default remedy to correct defective agency action"—is unwarranted in the event the 2013 Policy violates the APA. *Nat'l Parks Conservation Ass'n v. Semonite*, 925 F.3d 500, 501 (D.C. Cir. 2019) (per curiam). Because the court has determined only that HRSA's explanation in the 2013 Policy fails to satisfy what the APA requires for reasoned decisionmaking, nothing about this decision "require[s] the Court to also set aside the 1994 guidance." ECF No. 15-1, at 19. The agency may consider again whether the replenishment model, when utilized by DSHs subject to the GPO prohibition, complies with Section 340B. In that process, HRSA may adopt the same bottom-line view of the statute it did in the 2013 Policy, as long as the agency adheres to the APA and does not exceed its limited rulemaking authority over the Section 340B Program.

B. Because the 2013 Policy Is Arbitrary and Capricious, the Court Cannot Determine Whether It Is a Legislative or Interpretive Rule

As the court has explained, *see supra* Section IV.A, it need not resolve Premier's remaining APA challenges because it will set aside the 2013 Policy as arbitrary and capricious. The court nevertheless briefly explains its decision to withhold judgment on whether the 2013 Policy is a legislative or interpretive rule.

Under the APA, an agency "'[r]ule' . . . is defined broadly to include 'statement[s] of general or particular applicability and future effect' that are designed to 'implement, interpret, or prescribe law or policy.'" *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 95-96 (2015) (second alteration in original) (quoting 5 U.S.C. § 551(4)). When an agency "formulat[es], amend[s], or repeal[s] a rule," it engages in rulemaking. 5 U.S.C. § 551(5). The APA sets forth "notice-and-comment procedures" and "generally assumes that an agency's exercise of rulemaking must abide by those procedures unless certain exceptions apply." *City of Billings v.*

Transp. Sec. Admin., 153 F.4th 46, 51 (D.C. Cir. 2025). "One such exception is for 'interpretative' (or interpretive) rules, as opposed to legislative rules." *Id.* (quoting 5 U.S.C. § 553(b)(4)(A)).

"Legislative rules have the 'force and effect of law,' and usually bring about 'a substantive change in existing law or policy.'" *Id.* at 51-52 (citation omitted) (first quoting *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 215 (2016); then quoting *Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014)). "Interpretive rules, by contrast, ordinarily lack the force of law and instead only 'advise the public of the agency's construction of the statutes and rules which it administers.'" *Id.* at 52 (quoting *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995)). Put differently, interpretive rules "'"merely track[]" preexisting requirements and explain something the statute or regulation already required.'" *POET Biorefining, LLC v. Env't Prot. Agency*, 970 F.3d 392, 407 (D.C. Cir. 2020) (alteration in original) (quoting *Mendoza*, 754 F.3d at 1021).

The parties dispute whether the 2013 Policy is a legislative rule or an interpretive rule. Premier asserts that the 2013 Policy is a legislative rule because it "imposes a new legal prohibition" on regulated entities, ECF No. 11-1, at 14, and "effects a substantive change in existing law or policy" by departing from HRSA's prior interpretation of Section 340B, *id.* at 15 (quoting *Mendoza*, 754 F.3d at 1021). Moreover, Premier maintains that the 2013 Policy cannot be characterized as "interpretive" because it "does not mention, let alone interpret, any statutory provision of Section 340B." *Id.* at 16. And if the 2013 Policy is a legislative rule, Premier argues that HRSA lacked the authority to enact it because Section 340B only allows the agency to issue legislative rules in limited circumstances, none of which applies here—and that, at a minimum, HRSA was required to go through notice-and-comment rulemaking. *Id.* at 16-19.

For their part, Defendants assert that the 2013 Policy is an interpretive rule that is exempt from many of the APA's procedural rulemaking requirements. ECF No. 15-1, at 11-14; ECF

No. 21, at 1-6. Applying the D.C. Circuit's test from *American Mining Congress v. Mine Safety & Health Administration*, 995 F.2d 1106 (D.C. Cir. 1993), Defendants argue the 2013 Policy is interpretive because it reiterates the statutory GPO prohibition, Section 340B itself provides a basis for enforcement action, HRSA did not publish the 2013 Policy in the Code of Federal Regulations or invoke any general legislative authority, and HRSA did not "amend[] a prior legislative rule" as no earlier one existed. ECF No. 15-1, at 13 (alteration in original) (quoting *Am. Mining Cong.*, 995 F.2d at 1112); *see id.* at 12-14. If Defendants are correct, HRSA's decision to forego notice and comment for the 2013 Policy complied with the APA's procedural requirements. *See* 5 U.S.C. § 553(b)(A); *Mortg. Bankers Ass'n*, 575 U.S. at 96.

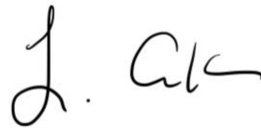
It is a close question whether the 2013 Policy is a legislative rule or an interpretive rule. On one hand, the 2013 Policy could potentially be read to "speak with the force of law." *Nat. Res. Def. Council v. Wheeler*, 955 F.3d 68, 83 (D.C. Cir. 2020). It declares conduct unlawful, prohibits certain covered entities from using the replenishment model, and warns that any violations will be met with sanctions. *See Mendoza*, 754 F.3d at 1021 (holding that a rule that "substantively affect[ed] the regulated public" and "set forth the agency's enforcement plan" was a legislative rule). On the other hand, the 2013 Policy can also "fairly be viewed as interpreting—even incorrectly—a statute or regulation," *POET Biorefining*, 970 F.3d at 408 (quoting *Cent. Tex. Tel. Co-op., Inc. v. Fed. Commc'ns Comm'n*, 402 F.3d 205, 212 (D.C. Cir. 2005)), even though HRSA's interpretive work is unreasoned and unexplained, *id.* at 409-10 (applying arbitrary-and-capricious standard to an interpretive rule); *see supra* Section IV.A. The 2013 Policy certainly purports to "advise the public of [HRSA's] construction of the statutes and rules which it administers." *POET Biorefining*, 970 F.3d at 407 (quoting *Mortg. Bankers Ass'n*, 575 U.S. at 97). And, interpretive rules "may articulate even relatively detailed legal obligations"

as long as they are "fairly drawn from underlying statutes or regulations." *Id.* at 408. This case illustrates why "[t]he 'line between interpretive and legislative rules' is 'fuzzy' and 'enshrouded in considerable smog.'" *Nat. Res. Def. Council*, 955 F.3d at 83 (quoting *Am. Mining Cong.*, 995 F.2d at 1108).

Having considered the parties' arguments and the administrative record, and in light of the court's conclusion that the 2013 Policy is arbitrary and capricious and must be vacated, the court declines to resolve the parties' dispute about the legislative or interpretive nature of the policy. *See Stellacom, Inc. v. United States*, 783 F. Supp. 647, 656 (D.D.C. 1992) (finding no need to resolve a challenge to notice-and-comment procedures after granting summary judgment to the plaintiff on the ground that the agency's regulation was arbitrary, capricious, and contrary to law); *cf. Cook v. Food & Drug Admin.*, 733 F.3d 1, 11 (D.C. Cir. 2013) (declining to consider whether agency action was arbitrary and capricious after determining that it was contrary to law); *Jicarilla Apache Nation v. U.S. Dep't of Interior*, 613 F.3d 1112, 1120-21 (D.C. Cir. 2010) (explaining that the court would "decline to consider" a third challenge to the agency's action after holding the action to be arbitrary and capricious on two separate grounds). Whether the 2013 Policy is a legislative rule or an interpretive rule turns partly on whether HRSA was interpreting Section 340B and its prior notices and whether the agency previously had permitted replenishment models for hospitals subject to the GPO prohibition. Notwithstanding the parties' efforts to distill the "smog," *Am. Mining Cong.*, 995 F.2d at 1108, the precise reasons why the 2013 Policy is arbitrary and capricious—HRSA's failure to provide any statutory interpretation, explain its prior guidance documents, and describe its pre-2013 policies concerning replenishment models—counsel against deciding the issue on this administrative record. As the court has explained, *see supra* pp. 21-22, HRSA is free to issue an interpretive rule on the GPO prohibition that complies with the APA.

V. CONCLUSION

For the foregoing reasons, the court will grant Premier's Motion for Summary Judgment, ECF No. 11, as it concerns the arbitrary-and-capricious challenge to the 2013 Policy and deny the remainder of the motion as moot, and the court will deny Defendants' Cross-Motion for Summary Judgment, ECF No. 15, as to whether the 2013 Policy is arbitrary or capricious and deny the remainder of the motion as moot. A contemporaneous order will issue.



LOREN L. ALIKHAN
United States District Judge

Date: March 31, 2026