**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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| HIV AND HEPATITIS POLICY INSTITUTE, et al.,<br>Plaintiffs,<br><br>v.<br><br>UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,<br>Defendants. | Civil Action No. 1:22-cv-2604 (JDB) |

**NOTICE OF APPEAL**

Notice is hereby given that Defendants United States Department of Health and Human Services, Xavier Becerra, in his official capacity as Secretary of Health and Human Services, the Centers for Medicare & Medicaid Services ("CMS"), and Chiquita Brooks-LaSure, in her official capacity as Administrator of CMS, hereby appeal to the United States Court of Appeals for the D.C. Circuit from the memorandum opinion (Dkt. No. 42) and order (Dkt. No. 41) entered by the Court on September 29, 2023.

Dated: November 28, 2023

Respectfully submitted,

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*/s/ Carol Federighi*
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**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

**HIV AND HEPATITIS POLICY INSTITUTE et al.,**
**Plaintiffs,**
**v.**
**UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES et al.,**
**Defendants.**

**Civil Action No. 22-2604 (JDB)**

**ORDER**

Upon consideration of [13] plaintiffs' motion for summary judgment and [27] defendants' cross-motion for summary judgment, and the entire record herein, and for the reasons stated in the accompanying Memorandum Opinion issued on this date, it is hereby

**ORDERED** that [13] plaintiffs' motion for summary judgment is **GRANTED**; it is further

**ORDERED** that [27] defendants' cross-motion for summary judgment is **DENIED**; it is further

**ORDERED** that the HHS Notice of Benefit and Payment Parameters for 2021 is **VACATED** to the extent that it amends 42 C.F.R. § 156.130(h), see 85 Fed. Reg. 29164, 29261 (May 14, 2020), and that the matter is **REMANDED** to defendants for further consideration consistent with the Memorandum Opinion issued on this date; and it is further

**ORDERED** that [8] defendants' motion to dismiss is **DENIED** as moot.

**SO ORDERED.**

/s/
JOHN D. BATES
United States District Judge

Dated: September 29, 2023

**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

**HIV AND HEPATITIS POLICY INSTITUTE et al.,**
**Plaintiffs,**
**v.**
**UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES et al.,**
**Defendants.**

**Civil Action No. 22-2604 (JDB)**

# MEMORANDUM OPINION

Plaintiffs, three individuals and three patient advocacy groups, challenge a rule promulgated by defendants, the U.S. Department of Health and Human Services ("HHS"), its component agency the Centers for Medicare and Medicaid Services ("CMS"), and the leadership of those agencies (collectively, the "agencies"). This rule affirmatively permits, but does not require, health insurance issuers and group health plans (collectively, "insurers") to decline to credit certain financial assistance provided to patients by drug manufacturers when calculating whether those patients have met their cost-sharing obligations under the Affordable Care Act. See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans, 85 Fed. Reg. 29164, 29230–35, 29261 (May 14, 2020) (codified at 45 C.F.R. § 156.130(h)) ("2021 NBPP").[1] Plaintiffs allege that the rule conflicts with the Affordable Care Act's statutory definition of "cost sharing," conflicts with the agencies' preexisting regulatory definition of "cost sharing," and is arbitrary and capricious.

[1] The full "Notice of Benefit and Payment Parameters for 2021" spans ninety-nine pages in the Federal Register. References to the "2021 NBPP" throughout this opinion are only to the portion challenged by plaintiffs.

Before the Court are the parties' cross-motions for summary judgment. For the reasons that follow, the Court concludes that the 2021 NBPP must be set aside based on its contradictory reading of the same statutory and regulatory language and the fact that the agencies have yet to offer a definitive interpretation of this language that would support the rule. The Court will thus grant plaintiffs' motion, deny the agencies' cross-motion, and vacate the challenged rule.

## Background

### I. Statutory and Factual Background

In 2010, Congress enacted the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) ("ACA"), in an effort to "increase the number of Americans covered by health insurance and decrease the cost of health care." Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 538 (2012). Among its various provisions, the ACA sets an annual cap on the amount that insurers can require insured individuals to pay out of pocket for their medical expenses. See 42 U.S.C. § 18022(c)(1); see also id. § 300gg-6(b); 2021 NBPP, 85 Fed. Reg. at 29229 (setting cost-sharing cap for 2021 at $8,550 for individual plans and $17,100 for family plans). Once this annual "cost sharing" cap is reached, the insurer is solely responsible for covering the insured individual's remaining medical expenses that year. See 42 U.S.C. § 18022(c)(1). The statute defines "cost sharing" as follows:

> The term "cost-sharing" includes—(i) deductibles, coinsurance, copayments, or similar charges; and (ii) any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of Title 26) with respect to essential health benefits covered under the plan.

Id. § 18022(c)(3)(A).

A deductible is "the portion of the loss [under an insurance policy] to be borne by the insured before the insurer becomes liable for payment." Deductible, Black's Law Dictionary (9th ed. 2009). Coinsurance is "[i]nsurance under which the insurer and insured jointly bear

responsibility." Coinsurance, id. And a copayment is "[a] fixed amount that a patient pays to a healthcare provider according to the terms of the patient's health plan." Copayment, id. Copayments are typically low, flat fees required when picking up a prescription drug or accessing medical care, while coinsurance payments are assessed as a percentage of the overall cost and thus may be much higher. See Pls.' Mem. Supp. Summ. J. [ECF No. 13-1] ("Pls.' Mot.") at 4 n.2 (citing public-facing agency guidance).

Some drug manufacturers offer direct "manufacturer assistance"—financial support to patients to pay for specific prescription drugs. See, e.g., 2021 NBPP, 85 Fed. Reg. at 29230. In one common setup, a drug manufacturer may provide a patient with a coupon that, when presented to a pharmacy or other point of sale, directs the pharmacy to bill all or part of the patient's copayment or coinsurance obligations to the drug manufacturer instead of the patient. See id. at 29234 (providing example of patient paying a $50 copay with $30 cash and a $20 coupon); Admin. R. App. [ECF No. 40-2] ("AR") at 2790–91 (describing the typical billing process as (1) the pharmacy submitting an electronic claim to the insurer for the drug, (2) the insurer processing the claim and sending a response indicating what portion of the payment is to be paid by the patient as cost-sharing, (3) the pharmacy billing the third-party assistance provider for all or part of that cost-sharing obligation, and (4) the patient paying any remaining balance); id. at 2768–69 ("The pharmacy receives the same payment it would for each drug dispensed, regardless of whether cost-sharing assistance is applied."). Other direct manufacturer assistance programs include "pre-paid debit cards for the payment of cost-sharing . . . and cash or check reimbursement to patients for their cost-sharing for a specific drug." AR at 2270 n.4; see id. at 2791 (similar). The through-line is some payment by the drug manufacturer to subsidize the patient's purchase of the drug at the

point of sale. See, e.g., id. at 2790–91; see also id. at 2270 n.4 (comment from national insurers' organization describing these programs as "funded by drug manufacturers").

Supporters of manufacturer assistance argue that these programs help patients—particularly those suffering from rare or costly conditions—afford drugs, which improves health outcomes by promoting adherence to existing medication regimens. See, e.g., 2021 NBPP, 85 Fed. Reg. at 29234; AR at 3569–71. Critics contend that manufacturer assistance can be used by drug manufacturers to artificially inflate demand for their drugs, thus distorting the market and increasing overall healthcare costs. See, e.g., 2021 NBPP, 85 Fed. Reg. at 29234; AR at 2271–72.

In response to manufacturer assistance, some insurers have instituted "copay accumulator" programs. Under these programs, patients are still able to utilize manufacturer assistance to pay for medications, but the value of this assistance is not credited toward patients' deductibles and annual cost-sharing maximums. See, e.g., 2021 NBPP, 85 Fed. Reg. at 29233. Take this stylized example, with assumptions of a $6,000 cost-sharing maximum, $4,000 in manufacturer assistance available, and a $2,000 monthly drug cost:

| | Without Copay Accumulator | | With Copay Accumulator | |
|---|---|---|---|---|
| Month | Paid by Patient | Paid by Mfr. Assistance | Paid by Patient | Paid by Mfr. Assistance |
| January | $0 | $2,000 | $0 | $2,000 |
| February | $0 | $2,000 | $0 | $2,000 |
| March | $2,000 | $0 | $2,000 | $0 |
| April | $0 | $0 | $2,000 | $0 |
| May | $0 | $0 | $2,000 | $0 |
| Rest of Year | $0 | $0 | $0 | $0 |
| **Total** | **$2,000** | **$4,000** | **$6,000** | **$4,000** |

Cf. AR at 1348 (providing similar example). With the copay accumulator program, the patient pays $4,000 more—the value of the non-credited manufacturer assistance—before reaching the $6,000 cost-sharing cap and having the insurer cover all costs for the remainder of the year. The

insurer thus collects $10,000 in cost-sharing payments as opposed to the $6,000 it would have collected in the absence of the copay accumulator.

## II. Regulatory Background

Prior to 2019, the agencies had not directly addressed the permissibility of copay accumulator programs. See 2021 NBPP, 85 Fed. Reg. at 29232 (noting that prior to the 2019 rulemaking, "federal rules did not explicitly state whether issuers and group health plans had the flexibility to determine how to factor in direct drug manufacturer support amounts towards the annual limitation on cost sharing"). The agencies had, however, defined the term "cost sharing" by regulation as follows:

> Cost sharing means any expenditure required by or on behalf of an enrollee with respect to essential health benefits; such term includes deductibles, coinsurance, copayments, or similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services.

45 C.F.R. § 155.20; see Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers, 77 Fed. Reg. 18310, 18445 (March 27, 2012) ("2012 Rule").

In April 2019, the agencies published the following rule regarding copay accumulators:

> Notwithstanding any other provision of this section, and to the extent consistent with state law, amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to enrollees to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have an available and medically appropriate generic equivalent are not required to be counted toward the annual limitation on cost sharing (as defined in paragraph (a) of this section).

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020, 84 Fed. Reg. 17454, 17568 (April 25, 2019) (codified at 45 C.F.R. § 156.130(h); version effective from June 24, 2019 to July 12, 2020) ("2020 NBPP"). In the preamble to the rule, the agencies explained that it was motivated by the market-distortive effect of manufacturer assistance

when a less expensive generic drug is available and expressed the view that "the overall intent of the [ACA] was to establish annual limitations on cost sharing that reflect the actual costs that are paid by the enrollee." Id. at 17544.

In response to commenters who recommended that all manufacturer assistance be excluded from counting toward the cost-sharing limit, the agencies explained that the rule was specifically intended to address market distortion in the generic-drug context and that "[w]here there is no generic equivalent available or medically appropriate, it is less likely that the manufacturer's coupon would disincentivize a lower cost alternative and thereby distort the market." Id. at 17545. The agencies further stated:

> Where there is no generic equivalent available or medically appropriate . . . amounts paid toward cost sharing using any form of direct support offered by drug manufacturers must be counted toward the annual limitation on cost sharing. We have added language to the regulation text to address this clarification.

Id. (emphasis added). But no such language was in fact added to the text of the final regulation. Compare Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020, 84 Fed. Reg. 227, 290–91 (proposed Jan. 24, 2019) ("Proposed 2020 NBPP"), with 2020 NBPP, 84 Fed. Reg. at 17568.

In short order, the agencies received "feedback . . . indicat[ing] there [was] confusion about whether the 2020 NBPP Final Rule require[d] plans and issuers to count the value of drug manufacturers' coupons toward the annual limitation on cost sharing, other than in circumstances in which there is a medically appropriate generic equivalent available." AR at 4320. The agencies, along with the Departments of Labor and the Treasury, issued a guidance document in August 2019 acknowledging this confusion. See id. at 4319–21. The guidance document also explained that, if read to apply outside the generic-drug context, the 2020 NBPP might conflict with certain IRS guidance regarding high deductible health plans. Id. at 4320. The agencies noted their intent

to address this issue in the 2021 NBPP and explained that, until then, they "[would] not initiate an enforcement action if an [insurer] excludes the value of drug manufacturers' coupons from the annual limitation on cost sharing, including in circumstances in which there is no medically appropriate generic equivalent available." Id. at 4321; see id. at 4320–21.

In May 2020, the agencies published the 2021 NBPP regulation at issue in this case:

> Notwithstanding any other provision of this section, and to the extent consistent with State law, amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs may be, but are not required to be, counted toward the annual limitation on cost sharing, as defined in paragraph (a) of this section.

2021 NBPP, 85 Fed. Reg. at 29261 (emphasis added); see 45 C.F.R. § 156.130(h). The preamble to the rule explained that it was motivated by the "confusion" engendered by the 2020 NBPP, the potential conflict with IRS guidance, and the desire to provide insurers with "flexibility." 2021 NBPP, 85 Fed. Reg. at 29231. The agencies stressed that the 2021 NBPP was intended to leave insurers "free to continue longstanding policies" and that the agencies "[did] not require and are not directing [insurers] to any specific practice with regards to how [manufacturer assistance is] treated with respect towards accumulators." Id. at 29233; see also, e.g., id. at 29232 ("[Insurers] need not make changes to how they have historically handled direct drug manufacturer support amounts.").

In the notice of proposed rulemaking for the 2021 NBPP, the agencies had "proposed to interpret the definition of cost sharing to exclude expenditures covered by drug manufacturer coupons." Id. at 29231; see also Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans, 85 Fed. Reg. 7088, 7136 (proposed Feb. 6, 2020). The agencies opted not to finalize this proposed interpretation, due at least in part to commenters who argued that the interpretation was

inconsistent with the existing regulatory definition of "cost sharing" at 45 C.F.R. § 155.20. See 2021 NBPP, 85 Fed. Reg. at 29230, 29234. Instead, the agencies concluded that "the term 'cost sharing' is subject to interpretation":

> For [health insurance] issuers who elect to include these amounts towards a consumer's annual limitation on cost sharing, the value of direct drug manufacturer support would be considered part of the overall charges incurred by the enrollee. For [health insurance] issuers who elect to not count these amounts towards the consumer's annual limitation on cost sharing, the value of the direct drug manufacturer support would be considered a reduction in the amount that the enrollee incurs or is required to pay.

Id. at 29234.

The agencies also responded to other comments expressing concern about aspects of the rule. As to the purported conflict with IRS guidance, the agencies explained their reasoning as to why this conflict "may exist." Id. at 29233. As to comments questioning why the rule was limited to direct support provided by drug manufacturers (as opposed to other forms of third-party support, such as amounts raised via crowdfunding), the agencies explained that they "currently ha[d] no evidence" that these other types of support had "similar distortive effects." Id. at 29234. And as to comments expressing concern that the affirmative authorization of copay accumulators would increase patients' out-of-pocket costs, the agencies noted that this cost impact would be limited if insurers not currently utilizing copay accumulators "continue[d] their current behavior," which the agencies "believe[d] [would] be the case." Id. at 29232. The agencies "acknowledge[d] the possibility" that the 2021 NBPP might lead some insurers to adopt copay accumulator programs but concluded that they could not "project this burden with sufficient certainty." Id.

## III. Procedural History

On August 30, 2022, the three organizational plaintiffs—the HIV and Hepatitis Policy Institute, the Diabetes Patient Advocacy Coalition, and the Diabetes Leadership Council—filed a

complaint challenging the 2021 NBPP and naming as defendants HHS, CMS, Xavier Becerra, in his official capacity as Secretary of HHS, and Chiquita Brooks-Lasure, in her official capacity as Administrator of CMS. Compl. [ECF No. 1]. The agencies moved to dismiss for lack of standing. Defs.' Mot. to Dismiss [ECF No. 8]. In response, plaintiffs filed an amended complaint adding three individual plaintiffs: Alyssa Dykstra, Katherine Mertens, and Cynthia Regan. Am. Compl. [ECF No. 10] ¶¶ 18–20.

On February 2, 2023, plaintiffs moved for summary judgment. Pls.' Mot. Plaintiffs advance three central arguments as to why the 2021 NBPP is unlawful and must be set aside. First, they argue that the 2021 NBPP conflicts with the ACA's statutory definition of "cost sharing" and that the new rule is not entitled to Chevron deference. See id. at 13–18. Second, plaintiffs contend that the 2021 NBPP "clashes even more starkly" with the agencies' preexisting regulatory definition of "cost sharing" at 45 C.F.R. § 155.20. Id. at 18; see id. at 18–21. Third, plaintiffs offer a host of reasons why the 2021 NBPP is arbitrary and capricious: (1) it gives the same statutory and regulatory language different meanings, (2) the "sole justification" for the rule is based on an erroneous view of the law, (3) the rule's analysis of costs to patients is irrational, (4) the agencies failed to explain their "reversal" from the 2020 NBPP and failed to take reliance interests on that earlier rule into account, and (5) the rule treats similarly situated cases differently without adequate justification. See id. at 21–38.

The agencies filed a cross-motion for summary judgment and opposed plaintiffs' motion. Defs.' Mem. Supp. Cross-Mot. Summ. J. & Opp'n to Pls.' Mot. [ECF No. 27-1] ("Defs.' Mot."). The agencies argue that the 2021 NBPP is not reviewable both because it is not "final agency action," 5 U.S.C. § 704, and because it is "agency action committed to agency discretion by law," id. § 701(a)(2). Defs.' Mot. at 12–16. They further contend that each of plaintiffs' challenges

lacks merit. See id. at 16–38. And the agencies assert that, even if the Court ultimately sets aside the 2021 NBPP as arbitrary and capricious, it should decline to interpret the statutory definition of "cost sharing" in the first instance. See id. at 39.

Plaintiffs filed a combined reply in support of their motion and opposition to the agencies' cross-motion, Reply Supp. Pls.' Mot. & Opp'n to Defs.' Cross-Mot. [ECF No. 32] ("Pls.' Reply"), and the agencies filed a reply in support of their cross-motion, Reply Supp. Defs.' Cross-Mot. [ECF No. 38] ("Defs.' Reply"). The Court also received three amicus curiae briefs supporting plaintiffs—one from Aimed Alliance and other healthcare policy and patient advocacy organizations, one from drug assistance coupon administrator TrialCard Incorporated, and one from Pharmaceutical Research and Manufacturers of America—and an amicus curiae brief supporting the agencies from America's Health Insurance Plans, Inc.

Both motions are now fully briefed and ripe for decision.

## Legal Standard

A moving party is entitled to summary judgment where it shows "that there is no genuine dispute as to any material fact and [that it] is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In an Administrative Procedure Act ("APA") challenge such as this, the "'entire case' . . . is a question of law," Am. Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1083 (D.C. Cir. 2001), and "[s]ummary judgment is the proper mechanism for deciding, as a matter of law, whether an agency action is supported by the administrative record and consistent with the APA standard of review," Hosp. for Special Surgery v. Becerra, Civ. A. No. 22-2928 (JDB), 2023 WL 5448017, at *4 (D.D.C. Aug. 24, 2023) (quoting Styrene Info. & Rsch. Ctr., Inc. v. Sebelius, 944 F. Supp. 2d 71, 77 (D.D.C. 2013)). Under the APA, a reviewing court will set aside final agency action that

is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); see id. § 704.

## Analysis

### I. Justiciability

#### A. Standing

The agencies concede that at least one of the individual plaintiffs added in plaintiffs' amended complaint has standing because she "takes a biologic medication . . . that currently has no generic equivalent." Defs.' Mot. at 10 n.1; see Am. Compl. ¶¶ 20, 81–82; Regan Decl. [ECF No. 13-4] ¶ 3. This plaintiff, Cynthia Regan, attests that due to her insurer's copay accumulator, manufacturer assistance she utilized in both 2022 and 2023 was not credited toward her cost-sharing maximum and she was required to pay additional money out of pocket before reaching the maximum. Regan Decl. ¶¶ 4–9.

To establish standing, "a plaintiff must show (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." TransUnion LLC v. Ramirez, 141 S. Ct. 2190, 2203 (2021). Here, the monetary harm suffered by Regan is a quintessential injury in fact. See id. at 2204. The agencies' authorization of the insurer's conduct satisfies the causation element, because "injurious private conduct is fairly traceable to the administrative action contested in the suit if that action authorized the conduct or established its legality." Animal Legal Def. Fund, Inc. v. Glickman, 154 F.3d 426, 441 (D.C. Cir. 1998) (en banc) (quoting Tel. & Data Sys., Inc. v. F.C.C., 19 F.3d 42, 47 (D.C. Cir. 1994)); see also, e.g., Consumer Fed'n of Am. v. F.C.C., 348 F.3d 1009, 1012 (D.C. Cir. 2003). And "[i]t follows that the injury is also redressable." Consumer Fed'n of Am., 348 F.3d at 1012. Even assuming the

2020 NBPP does not prohibit the challenged conduct—such that vacatur of the 2021 NBPP would render the conduct unregulated as opposed to unlawful—"[o]n remand, the [agencies] could adopt [plaintiffs'] position and force [insurers] to change [their] practices." Id. While "remand would not entitle [plaintiffs] to such relief, it 'would constitute a necessary first step.'" Id. (some internal quotations omitted) (quoting Tel. & Data Sys., Inc., 19 F.3d at 47).

Hence, Regan has standing. Because she does, the Court "need not consider the standing of the other plaintiffs." Carpenters Indus. Council v. Zinke, 854 F.3d 1, 9 (D.C. Cir. 2017) (quoting Mountain States Legal Found. v. Glickman, 92 F.3d 1228, 1232 (D.C. Cir. 1996)).[2]

**B. Administrative Reviewability**

The agencies argue that the 2021 NBPP is unreviewable either as agency action that is not "final," 5 U.S.C. § 704, or as "agency action committed to agency discretion by law," id. § 701(a)(2). Neither contention is ultimately persuasive.

Under the APA, judicial review is limited to "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. To be "final," agency action must generally meet two requirements: (1) it "must mark the consummation of the agency's decisionmaking process" rather than being "of a merely tentative or interlocutory nature" and (2) it "must be one by which rights or obligations have been determined, or from which legal consequences will flow." U.S. Army Corps of Eng'rs v. Hawkes Co., 578 U.S. 590, 597 (2016) (quoting Bennett v. Spear, 520 U.S. 154, 177–78 (1997)). The agencies concede that the first of these requirements is met. Defs.' Mot. at 12.

[2] The agencies moved to dismiss plaintiffs' original complaint for lack of standing. Plaintiffs have since filed the amended complaint adding Dykstra, Mertens, and Regan as individual plaintiffs. The Court will thus deny the motion to dismiss as moot. See, e.g., Bowe-Connor v. Shinseki, 923 F. Supp. 2d 1, 3 n.1 (D.D.C. 2013).

The agencies argue that the second requirement is not satisfied because the 2021 NBPP "is essentially a decision to decline to set rules" and "does not require regulated entities to make any changes to prior practices or impose any consequences on the choices regulated parties make in this regard." Id. at 12–13. They highlight the rule preamble's explanation that regulated parties "need not make changes," remain free to "continue longstanding policies," and are afforded "flexibility." Id. at 13 (quoting 2021 NBPP, 85 Fed. Reg. at 29231–32). And they invoke case law noting that this requirement is commonly met where an agency action "impose[s] 'obligations, prohibitions or restrictions on regulated entities'" or subjects them to "the risk of 'significant criminal and civil penalties'"—conditions that are not present here. Id. (quoting Sierra Club v. Env't Prot. Agency, 955 F.3d 56, 63 (D.C. Cir. 2020)); see also, e.g., Nat'l Min. Ass'n v. McCarthy, 758 F.3d 243, 252 (D.C. Cir. 2014).

The agencies are correct, but only to a point. They miss an important strand of case law: agency action may also have "legal consequences" (and thus be final) where it meaningfully circumscribes regulators' discretion and affords a safe harbor to regulated parties. See Scenic Am., Inc. v. United States Dep't of Transp., 836 F.3d 42, 56 (D.C. Cir. 2016) (concluding that guidance memorandum had legal consequences, and thus was final agency action, because it "withd[rew] some of the discretion . . . [regulators] previously held," thus "creat[ing] a safe harbor" such that the agency could not disapprove of conduct authorized by the memorandum); see also, e.g., POET Biorefining, LLC v. Env't Prot. Agency, 970 F.3d 392, 405 (D.C. Cir. 2020) ("The Guidance carries legal consequences because it withdraws some of the discretion [a prior rule] afforded EPA . . . ."); cf. Cal. Cmtys. Against Toxics v. Env't Prot. Agency, 934 F.3d 627, 637–38 (D.C. Cir. 2019) (distinguishing case from the "circumstance where the action at issue may be legally consequential because its binds agency staff").

Here, the 2021 NBPP affirmatively authorizes the use of copay accumulator programs. See 85 Fed. Reg. at 29261. In so doing, it bars the agencies from instituting enforcement actions against insurers who utilize these programs so long as the rule is in effect. This "legal consequence[]" satisfies Bennett's second requirement, and thus the 2021 NBPP is a final agency action. Hawkes Co., 578 U.S. at 597 (quoting Bennett, 520 U.S. at 178).

The fact that the 2021 NBPP was published in the Code of Federal Regulations ("CFR") following notice and comment reinforces this conclusion. While publication in the CFR is not dispositive in the finality inquiry, see Am. Tort Reform Ass'n v. Occupational Safety & Health Admin., 738 F.3d 387, 394 (D.C. Cir. 2013), it is another indicator that the rule has legal effect and thus constitutes final agency action, see Ass'n of Flight Attendants-CWA, AFL-CIO v. Huerta, 785 F.3d 710, 717 (D.C. Cir. 2015); see also 44 U.S.C. § 1510(a) (designating for publication in the CFR "documents . . . having general applicability and legal effect").

The agencies also argue that the 2021 NBPP is unreviewable because it is "agency action . . . committed to agency discretion by law." 5 U.S.C. § 701(a)(2). They contend that the rule "represents an exercise of [their] discretion not to regulate in certain situations," Defs.' Mot. at 15, and that the Court has "no meaningful standard against which to judge [this] exercise of discretion," id. (quoting Webster v. Doe, 486 U.S. 592, 600 (1988)). But, as plaintiffs observe and as discussed above, the 2021 NBPP is not merely a decision not to regulate. See Pls.' Reply at 7. Rather, it affirmatively authorizes two courses of conduct and permits regulated parties to choose between them. Plaintiffs are not challenging the agencies' decision whether or not to regulate, but rather the product of the agencies' decision to regulate. And as to the agencies' affirmative authorization of copay accumulators, there is clearly a "meaningful standard" against which to

judge the action's legality: the statutory and regulatory definitions of "cost sharing," as well as the APA's well-established arbitrary and capricious test.

The Court thus concludes that the 2021 NBPP is reviewable under the APA.

## II. Merits

Plaintiffs contend that the 2021 NBPP must be vacated because (1) it conflicts with the ACA's statutory definition of "cost sharing," (2) it conflicts with the agencies' preexisting regulatory definition of "cost sharing," and (3) it is arbitrary and capricious for a variety of reasons, including that it defines the same statutory and regulatory language in two conflicting ways. As discussed below, the Court will set aside the 2021 NBPP based on both its contradictory reading of the same statutory and regulatory language and the fact that the agencies have yet to offer a definitive interpretation of this language that would support their authorization of copay accumulators. The Court declines to reach plaintiffs' remaining arguments as to why the 2021 NBPP is arbitrary and capricious.

### A. Contradictory Textual Interpretation

The agencies have yet to adopt a single interpretation of either the statutory or regulatory definition of "cost sharing" as applied to manufacturer assistance. See 2021 NBPP, 85 Fed. Reg. at 29234. Rather, the 2021 NBPP authorizes insurers to either count, or not count, such assistance "toward the annual limitation on cost sharing"—that is, to treat it as either within or without the definitions of "cost sharing." Id. at 29261. The agencies justified these dual authorizations based on two different, and contradictory, readings of the same statutory and regulatory text:

> For [health insurance] issuers who elect to include these amounts towards a consumer's annual limitation on cost sharing, the value of direct drug manufacturer support would be considered part of the overall charges incurred by the enrollee. For [health insurance] issuers who elect to not count these amounts towards the consumer's annual limitation on cost sharing, the value of the direct drug

> manufacturer support would be considered a reduction in the amount that the enrollee incurs or is required to pay.

Id. at 29234.

Plaintiffs challenge as arbitrary and capricious this interpretation of the same statutory and regulatory provisions as having two different meanings, to be chosen at the discretion of regulated parties. See Pls.' Mot. at 21; Pls.' Reply at 14–16. The Court agrees. The Supreme Court has rejected the "dangerous principle that . . . the same statutory text" can be given "different meanings in different cases." Clark v. Martinez, 543 U.S. 371, 386 (2005); accord United States v. Santos, 553 U.S. 507, 522–23 (2008) (plurality opinion); cf. Walter O. Boswell Mem'l Hosp. v. Heckler, 749 F.2d 788, 798–99 (D.C. Cir. 1984) (noting that "[i]t would be arbitrary and capricious for HHS to bring varying interpretations of the statute to bear" based "on mere expedience"). This is not a case where the agency has interpreted a term differently when it appears in different sections of a statute; here, the dueling authorizations are based on the very same provision. Cf. Verizon California, Inc. v. F.C.C., 555 F.3d 270, 276 (D.C. Cir. 2009).

The agencies offer little in the way of pushback to this conclusion, not even addressing the argument in their reply brief. They first assert that they "are permitted to promulgate regulations interpreting ambiguous statutes without having to resolve all possible ambiguity." Defs.' Mot. at 25 (quoting Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives, 920 F.3d 1, 34 (D.C. Cir. 2019)). But the issue here is not that the agencies have not yet definitively interpreted the definition of "cost sharing": it is that they have authorized two courses of conduct based on two fundamentally contradictory readings of that definition. The agencies also generally invoke the importance of choice in the health insurance context and the role of state-level regulation, and claim that the 2021 NBPP "merely extends this provision of choice to the question of whether to

count manufacturer financial assistance as cost sharing." Id. at 26. Again, this is not responsive to the fact that the rule rests on contradictory interpretations of the same text.

Hence, the Court concludes that the 2021 NBPP is arbitrary and capricious in its authorization of conduct (at the insurer's choice) based on contradictory interpretations of the same statutory and regulatory provisions and must be set aside on that basis.

**B. Statutory Definition**

Plaintiffs urge the Court to conclude that the ACA's definition of "cost sharing" unambiguously encompasses manufacturer assistance. See Pls.' Mot. at 13–18. The agencies, for their part, do not offer a preferred interpretation of the statute but rather defend their prior conclusion that the statute is ambiguous. See Defs.' Mot. at 16–23. The agencies concede that, because they have not offered an authoritative interpretation of the statute, Chevron "step two" deference is not warranted. Defs.' Mot. at 23 n.2; see also Pls.' Mot. at 17.

In assessing whether the statutory language is ambiguous—such that remand to the agencies to interpret it in the first instance would be warranted—the Court begins, as it must, with the text. See, e.g., Bartenwerfer v. Buckley, 143 S. Ct. 665, 671 (2023). The ACA defines "cost sharing" as follows:

> The term "cost-sharing" includes—(i) deductibles, coinsurance, copayments, or similar charges; and (ii) any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of Title 26) with respect to essential health benefits covered under the plan.

42 U.S.C. § 18022(c)(3)(A). This definition does not expressly speak to the treatment of manufacturer assistance, so the Court will employ the traditional tools of statutory construction.

The Court will interpret the three enumerated terms in the first clause in light of their "plain meaning at the time of enactment." Tanzin v. Tanvir, 141 S. Ct. 486, 491 (2020). Both parties cite Black's Law Dictionary as reflective of this meaning. See Pls.' Mot. at 14; Defs.' Mot. at 19.

This analysis yields competing inferences. On the one hand, Black's defines "deductible" as "the portion of the loss to be borne by the insured." Deductible, Black's Law Dictionary (9th ed. 2009) (emphasis added). This language is most naturally read as speaking to "loss"—i.e., costs—actually "borne" by the insured herself. Such a reading is reinforced by the definition of "copayment" as "[a] fixed amount that a patient pays to a healthcare provider." Copayment, id. (emphasis added). On the other hand, Black's defines "coinsurance" as "[i]nsurance under which the insurer and insured jointly bear responsibility." Coinsurance, id. (emphasis added). This lends support to plaintiffs' central argument that these terms and the overall statutory definition of "cost sharing" speak only to "the legal responsibility for payment, not where the insured gets the money to satisfy that responsibility." Pls.' Mot. at 14. The phrase "any other expenditure required of an insured individual" in the second statutory clause—which plaintiffs argue should read back to define the terms in the first clause—also supports this theory. Id. (citing Dong v. Smithsonian Inst., 125 F.3d 877, 880 (D.C. Cir. 1997)); see id. at 14–15; Pls.' Reply at 11.

Plaintiffs also argue that the second clause's definition of the other types of expenditures that count toward "cost sharing" supports their position. The clause cross-references 26 U.S.C. § 223(d)(2), which defines "qualified medical expenses," in relevant part, as amounts paid for medical care "but only to the extent such amounts are not compensated for by insurance or otherwise." Id. (emphasis added). Plaintiffs argue that the presence of this limitation (which would presumably exclude manufacturer assistance) in the second clause but not the first clause evinces Congress's intent that the first clause of the definition not be so limited. Pls.' Mot. at 15. Plaintiffs are correct that when "'Congress includes particular language in one section of a statute but omits it in another section' . . . [courts] generally take the choice to be deliberate." Bartenwerfer, 143 S. Ct. at 673 (quoting Badgerow v. Walters, 142 S. Ct. 1310, 1318 (2022)). But

this exclusionary presumption "is not absolute": "[c]ontext counts, and it is sometimes difficult to read much into the absence of a word that is present elsewhere in a statute." Id. "The more apparently deliberate the contrast, the stronger the inference." Field v. Mans, 516 U.S. 59, 75 (1995). Here, the potentially limiting language is present in a cross-reference to another statute, weakening the inference. And there is also a tension inherent in plaintiffs' argument: they argue that the "required of" language in the second clause must reflect back on the terms in the first clause, but offer no explanation as to why, under that logic, the limiting language from § 223(d)(2) should not also reflect back.

To add to the mix, the agencies contend that manufacturer assistance may not even be a "cost" within the statutory definition in the first place, because "the value of the direct drug manufacturer support could be viewed as not representing costs incurred by or charged to enrollees" but rather "a reduction . . . in the amount that the enrollee is required to pay . . . to obtain the drug." Defs.' Mot. at 17 (quoting 2021 NBPP, 85 Fed. Reg. at 29234); see also Defs.' Reply at 3–4.

Finally, plaintiffs contend that "the patient-benefitting purpose of the ACA" should serve as "an interpretive tie-breaker." Pls.' Reply at 10 n.4. But while benefiting individual patients is no doubt one purpose of the statute, the statute was also intended to "decrease the cost of health care." Nat'l Fed'n of Indep. Bus., 567 U.S. at 538. And the agencies undertook the 2021 NBPP rulemaking in part due to concern that manufacturer assistance may distort the market and "add significant long-term costs to the health care system." 2021 NBPP, 85 Fed. Reg. at 29234.

Having considered these arguments and the statutory text, the Court concludes that the ACA's definition of "cost sharing" does not speak clearly as to the treatment of manufacturer assistance. And "[i]n a suit challenging agency action, 'it is not for the court to choose between

competing meanings' of an ambiguous statute when the agency charged with its administration has not weighed in first." Teva Pharms. USA, Inc. v. Food & Drug Admin., 441 F.3d 1, 4 (D.C. Cir. 2006) (some internal quotations omitted) (quoting PDK Labs., Inc. v. D.E.A., 362 F.3d 786, 798 (D.C. Cir. 2004)); see also, e.g., Prill v. N.L.R.B., 755 F.2d 941, 942 (D.C. Cir. 1985); Hosp. of Barstow, Inc. v. N.L.R.B., 820 F.3d 440, 445 (D.C. Cir. 2016) (collecting cases).

The Court rejects plaintiffs' contention that this principle does not apply here. See Pls.' Reply at 24. While the agencies have offered potential interpretations of the statute, they have not made a final judgment between these competing meanings so as to "tee[] up" that interpretive question for the Court's review. Id. And while the original rationale for the doctrine—remand "when an agency incorrectly concludes that Congress mandated a particular regulatory interpretation of a statute"—is not implicated here, subsequent case law makes clear that the underlying principle applies more broadly. Noble Energy, Inc. v. Salazar, 671 F.3d 1241, 1246 n.5 (D.C. Cir. 2012); see also, e.g., Child.'s Hosp. & Rsch. Ctr. of Oakland, Inc. v. N.L.R.B., 793 F.3d 56, 59 (D.C. Cir. 2015).

Hence, the Court will vacate the 2021 NBPP and remand to permit the agencies to interpret the statutory definition in the first instance. Vacatur is appropriate here. An "inadequately supported rule . . . need not necessarily be vacated," because an "agency may be able to rehabilitate its rule on remand, and the consequences of vacatur 'may be quite disruptive.'" Shands Jacksonville Med. Ctr., Inc. v. Azar, 959 F.3d 1113, 1118 (D.C. Cir. 2020) (quoting Allied-Signal, Inc. v. U.S. Nuclear Regul. Comm'n, 988 F.2d 146, 150–51 (D.C. Cir. 1993)). But here, whatever interpretation the agencies adopt on remand cannot conceivably "rehabilitate" the 2021 NBPP, because the 2021 NBPP rests on two contradictory interpretations of the statute. Tellingly, the

agencies do not even argue for remand without vacatur. See Defs.' Mot. at 39; see generally Defs.' Reply.

**C. Regulatory Definition**

Building on their statutory arguments, plaintiffs contend that the 2021 NBPP must be set aside because its approval of copay accumulators "clashes even more starkly" with the agencies' preexisting regulatory definition of "cost sharing." Pls.' Mot at 18; see id. at 18–20; Pls.' Reply at 12–14. The Court agrees that, based on the arguments presented by the parties, the 2021 NBPP would conflict with the regulatory definition. But there are difficult interpretive questions as to this definition that were not raised by the parties.

"[A]n agency action may be set aside as arbitrary and capricious if the agency fails to 'comply with its own regulations.'" Nat'l Env't Dev. Ass'ns Clean Air Project v. E.P.A., 752 F.3d 999, 1009 (D.C. Cir. 2014) (quoting Environmentel, LLC v. F.C.C., 661 F.3d 80, 85 (D.C. Cir. 2011)); see also, e.g., Pol'y & Rsch., LLC v. U.S. Dep't of Health & Hum. Servs., 313 F. Supp. 3d 62, 67 (D.D.C. 2018). Here, the agencies defined "cost sharing" under the ACA by regulation as follows:

> Cost sharing means any expenditure required by or on behalf of an enrollee with respect to essential health benefits; such term includes deductibles, coinsurance, copayments, or similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services.

45 C.F.R. § 155.20 (emphasis added). This regulation, enacted in 2012, predated the 2021 NBPP. See 2012 Rule, 77 Fed. Reg. at 18445.

Both parties appear to read the regulation as defining cost sharing as an "expenditure" by or on behalf of an enrollee. Pls. Mot. at 19; see Defs.' Mot. at 23–25 (not challenging plaintiffs' characterization). So read, the definition squarely encompasses manufacturer assistance: such assistance is an "expenditure" by drug manufacturers made "on behalf of an enrollee." 45 C.F.R.

§ 155.20; see Expenditure, Black's Law Dictionary (9th ed. 2009) ("A sum paid out."); Behalf, Black's Law Dictionary (11th ed. 2019) ("[O]n behalf of means 'in the name of, on the part of, as the agent or representative of.'"). The use of the term "any" lends further support to that conclusion. See, e.g., Lissack v. Comm'r, 68 F.4th 1312, 1320 (D.C. Cir. 2023) ("The Supreme Court has 'repeatedly explained' that 'the word "any" has an expansive meaning.'" (quoting Patel v. Garland, 142 S. Ct. 1614, 1622 (2022))).

The agencies' three rejoinders are not persuasive. First, the agencies argue that the 2021 NBPP's affirmative authorization of copay accumulators does not run afoul of this definition because the value of manufacturer assistance could "be viewed as representing a reduction, by drug manufacturers, in the amount that the enrollee is required to pay at the point of sale in order to obtain the drug." Defs.' Mot. at 24 (quoting 2021 NBPP, 85 Fed. Reg. at 29234). But regardless of whether manufacturer assistance represents a reduction in the amount a patient is required to pay (under the statutory definition), it would still be an "expenditure" by the drug manufacturer "on behalf of" that patient (under the regulatory definition).

The agencies further contend that the preexisting regulatory definition could be viewed as speaking to the "actual economic impact" on the drug manufacturer. Id. at 25. On this view, manufacturer assistance may be more easily characterized as a reduction in the price of the drug rather than a "cost" or an "expenditure" on behalf of a patient. But nothing in the regulatory definition indicates that "cost sharing" should be defined with reference to its underlying economic impact on third-party drug manufacturers. To the contrary, the text of the regulation—"any expenditure required by or on behalf of an enrollee"—makes clear that the locus of the inquiry is the patient. 45 C.F.R. § 155.20 (emphasis added). The statutory language—"any other

expenditure required of an insured individual"—is to the same effect. 42 U.S.C. § 18022(c)(3)(A) (emphasis added).

Finally, the agencies assert that manufacturer assistance "may not involve any 'expenditure[s]' on anyone's behalf" because "at least in some cases, the drug manufacturer may merely reduce the amount required to be paid by the purchaser." Defs.' Reply at 7. The agencies offer no factual support for this assertion regarding the mechanics of manufacturer assistance. And it is in tension with the 2021 NBPP and the administrative record, which indicate that manufacturer assistance involves a payment—an expenditure—by the drug manufacturer to a pharmacy or other point of sale. See, e.g., 2021 NBPP, 85 Fed. Reg. at 29234; AR at 2270 & n.4, 2768–69, 2790–91. But even accepting the agencies' premise, the 2021 NBPP would still conflict with the preexisting regulatory definition with respect to many forms of manufacturer assistance that do involve "expenditure[s]" by drug manufacturers.

Hence, on these arguments, the Court would conclude that the regulatory definition unambiguously requires manufacturer assistance to be counted as "cost sharing."

But the parties' reading is not the only, and perhaps not the best, literal reading of the text of the regulation. The Court agrees with the parties' implicit assumption that the likely intent of the regulation was to define "cost sharing" as costs that are (1) required of an enrollee and (2) paid by "or on behalf of" that enrollee. But that is not what the text of the regulation actually says. Instead, it defines cost sharing as "any expenditure required by or on behalf of an enrollee." 45 C.F.R. § 155.20. On the parties' reading, this means any expenditure either "required by" or "on behalf of" an enrollee. But an equally plausible reading of the language is any expenditure "required by" or "required . . . on behalf of" an enrollee.[3] This raises thorny questions about what

[3] Indeed, this may be the best reading of the words. See, e.g., Wronke v. Marsh, 787 F.2d 1569, 1574–75 (Fed. Cir. 1986) (concluding that, under rules of English grammar, the phrase "judicial proceedings resulting in an

it might mean for an expenditure to be "required"—whether by law, by an insurance plan, by contractual arrangement, or otherwise—"on behalf of" an enrollee. And there is a further wrinkle: the regulation defines cost sharing as an expenditure "required by" an enrollee, instead of the statutory "required of." It would be odd to think of the enrollee as the one "requiring" the expenditure, but that is what the word "by" implies. In sum, there are interpretive depths to this regulation that have yet to be plumbed.

These questions further support the Court's decision to remand to the agencies. Plaintiffs do not challenge this preexisting regulatory definition, and the parties have not briefed any of these questions. The Court will thus leave these questions to the agencies to grapple with in the first instance on remand.

**D. Remaining Arguments**

Because the Court will set aside the 2021 NBPP for the reasons stated above, it declines to reach plaintiffs' remaining arguments as to why the agencies acted arbitrarily and capriciously in promulgating the 2021 NBPP.[4]

acquittal based on the merits of the case or in an action having the same effect" must be read as "judicial proceedings resulting in an acquittal . . . or judicial proceedings resulting in an action having the same effect as an acquittal" (emphasis omitted)); cf. A. Scalia & B. Garner, Reading Law: The Interpretation of Legal Texts 147 (2012) ("When there is a straightforward, parallel construction that involves all nouns or verbs in a series, a prepositive . . . modifier normally applies to the entire series.").

[4] Plaintiffs' amended complaint seeks vacatur, a declaratory judgment, and an injunction. Am. Compl. at 28–29. In their summary judgment briefing, plaintiffs request only vacatur of the rule. Pls.' Mot. at 42; Pls.' Reply at 25. In light of that limited request and in the absence of any indication that the agencies will not abide by the Court's ruling, issuance of an injunction is not warranted at this juncture. See O.A. v. Trump, 404 F. Supp. 3d 109, 153–54 (D.D.C. 2019).

## III. Conclusion

For the foregoing reasons, the Court will grant plaintiffs' motion for summary judgment and will deny the agencies' cross-motion for summary judgment.[5] An accompanying Order will issue on this date.

/s/
JOHN D. BATES
United States District Judge

Dated: September 29, 2023

[5] The Court will vacate the 2021 NBPP to the extent that it amends 42 C.F.R. § 156.130(h). See 85 Fed. Reg. at 29261. Should the agencies need further clarification as to what rule is in effect while they consider the matter on remand, they may seek guidance from the Court.