IN THE 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. 1:22-cv-02604-JDB

MEMORANDUM IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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OTHER AUTHORITIES

Bear, Black's Law Dictionary (11th Ed. 2019) 19

Copayment, Black's Law Dictionary (11th Ed. 2019) 19

Insurance, Black's Law Dictionary (11th Ed. 2019) 19

INTRODUCTION

Agencies are not always required to regulate when a statute passed by Congress is ambiguous or leaves a gap. In the absence of a statutory directive commanding that the agency promulgate regulations, an agency "reasonably may decline to issue a . . . standard if it is uncertain about its efficacy." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 51 (1983). That is what occurred here. In the face of a statute that is silent as to whether amounts of drug manufacturer financial assistance (in the form of coupons, discount cards, or other mechanisms) constitute "cost sharing" and that can be read to permit either a yes or no answer, the Centers for Medicare & Medicaid Services ("CMS") of the United States Department of Health and Human Services ("HHS") reasonably declined to set a definitive rule in this regard. One year after an earlier attempt to regulate in this area, HHS, through CMS, promulgated a revised rule that deferred to states, and, as permitted by state law, to health insurance issuers and plans, to decide whether to count amounts of drug manufacturer financial assistance as cost sharing for the purposes of the annual federal limitation on cost sharing. Specifically, the rule provides that "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" applicable to that enrollee's insurance plan. 45 C.F.R. § 156.130(h).

Plaintiffs filed the present suit challenging HHS's decision not to set definitive standards in this area, claiming that is not "in accordance with law[,]" and is arbitrary and capricious under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2). Defendants are entitled to summary judgment. First, Plaintiffs' claims are nonjusticiable because the rule is not final agency action subject to review under the APA. *See id.* § 704. Because the rule declines to set definite requirements in this area and provides complete flexibility to states and, as permitted by

state law, issuers and plans, to determine how to treat manufacturer financial assistance for the purposes of the cost-sharing limit, it imposes no substantive obligations on any regulated party or member of the public, much less on Plaintiffs. In addition, the agency's decision whether to regulate in this area is agency action "committed to agency discretion by law" where there is no meaningful standard by which to judge the agency's exercise of its discretion. Hence, the decision is also unreviewable under 5 U.S.C. § 701(a)(2).

Second, even if Plaintiffs could overcome these justiciability hurdles, HHS properly concluded that the relevant statute is ambiguous as to whether the value of manufacturer financial assistance counts as cost sharing, and HHS's decision to permit flexibility in this area is not arbitrary or capricious. Its decision (1) does not conflict with its own regulation, which is also ambiguous, (2) is reasonable even though it permits different types of policies or plans, (3) was reasonably explained even though it represented a change in policy, and the impact on any reliance interests was adequately addressed, and (4) adequately assessed the potential effects on patient costs. In addition, (5) HHS was not required to consider the alternative proposed by Plaintiffs and reasonably declined to address other forms of patient assistance.

Accordingly, HHS considered the "relevant factors," made "rational" decisions on how to proceed, and "articulate[d] a satisfactory explanation for its action." *State Farm*, 463 U.S. at 43 (citations omitted). To the extent the decision is reviewable, therefore, the Court should uphold HHS's decision. However, should the Court agree that the statute is ambiguous, but conclude that the agency's decision is not reasonable or not reasonably explained, it should remand to the agency for further rulemaking, rather than attempting to impose its own interpretation of the statute.

BACKGROUND

I. STATUTORY BACKGROUND

In 2010 Congress enacted the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (the "Affordable Care Act"). Among other things, the Affordable Care Act generally requires employer-sponsored group health plans and health insurance issuers to ensure that any annual cost sharing imposed under their plans does not exceed specified limitations. *See* 42 U.S.C. §§ 300gg-6(b), 18022(c)(1). Cost sharing is defined to include "deductibles, coinsurance, copayments, or similar charges; and . . . 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).

II. THE 2020 NBPP

Given the high cost of some brand-name prescription medications, some drug manufacturers offer financial assistance programs that provide discounts on those drugs. *See* Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020, 84 Fed. Reg. 17,454, 17,545 (Apr. 25, 2019). But as these discount programs gained popularity, health plans and issuers, pharmacies, and other actors became concerned that the programs artificially increased demand for expensive drugs. By manipulating patients' out-of-pocket drug costs, manufacturers could decouple demand for a drug from the drug's price. This threatened to give manufacturers the power to increase the price of their most expensive drugs with impunity—and manufacturers could easily recover any revenue they lost from coupons by increasing the overall price of the drug, which increase would largely be borne by health plans.

Then, as drug prices rose, health plans would likely pass on at least some of those increased drug costs to other parts of the health system, including through increased premiums. *See* Administrative Record ("AR") 003728 (comment of Pharmaceutical Care Management Association that, because of the use of coupons, "manufacturers need only negotiate [with insurers] to the point of formulary inclusion"); AR003839 (comment of Anthem that coupons lead to "utilization and cost trends that contribute significantly to premium affordability challenges"); AR003983 (comment of CVS explaining drug coupons "ultimately increase[] cost for beneficiaries and the health care system as a whole by disguising the true cost of drugs"); AR004034-35 (Blue Cross Blue Shield Association comment that coupons "undercut issuers' ability to negotiate prices" and pointing to study that coupons increased the percentage of prescriptions filled with brand-name formulations by more than 60 percent).

Some health plans and issuers responded by declining to credit manufacturer financial assistance towards the maximum annual cost sharing that patients are required to pay under their health plans. *See, e.g.*, AR003728 (comment of Pharmaceutical Care Management Association that a third of employer health plans used accumulators); *see also* AR004076 (comment of PhRMA acknowledging trend). This sort of practice by health plans is sometimes referred to as an "accumulator adjustment program" or "accumulator program." Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021, 85 Fed. Reg. 29,164, 29,233 (May 14, 2020); FAC ¶¶ 9-10, 36.

As a result of the application of such accumulator adjustment programs, an affected patient will have to pay the equivalent of the discount amount in additional out-of-pocket costs before his or her cost-sharing limit is reached. However, it is not accurate to say, as Plaintiffs do throughout their brief, that insurance companies "collect" the value of manufacturer coupons

through their accumulator adjustment programs. *See* Memorandum in Support of Plaintiffs' Motion for Summary Judgment, ECF No. 13-1 ("Pls.' Mem.") at 2, 7. Rather, accumulator adjustment programs allow issuers and plans to delay incurring coverage liability until after the enrollee has satisfied the amount of the required cost sharing without including the amount of the manufacturer assistance. *See* AR001180; *see also* Pls' Mem. 3 (correctly describing effect of accumulator adjustment programs as "delaying . . . the point at which the insurer will be forced to cover 100% of the patient's medical costs"). Therefore, although accumulator adjustment programs "seek to shift drug costs from insurers to patients and manufacturers," *Pharm. Rsch. & Mfrs. of Am. v. Becerra*, No. 1:21-CV-1395 (CJN), 2022 WL 1551924, at *2 (D.D.C. May 17, 2022), they do not result in insurance companies "collecting" the coupon amounts.

The dispute between drug manufacturers and health plans led the American Medical Association to express frustration. It believed that "co-pay cards and other forms of economic assistance are needed for patients given the current state of the prescription drug marketplace," but it was also "very concerned that co-pay cards in particular further distort the market" and "enable pharmaceutical manufacturers to keep prices high." AR004089; *see also* AR003945 (comment of American Hospital Association supporting efforts to curb use of manufacturer coupons).

In 2019, HHS (through CMS) promulgated a regulatory change to address the effect of drug manufacturer financial assistance for prescription drugs on the cost-sharing limits under the Affordable Care Act. 84 Fed. Reg. at 17,544-46 (the "2020 NBPP" or "2020 Rule"); *see also* 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). HHS first noted that the Affordable Care Act "does not speak directly to the accounting and use of drug manufacturer coupons to the

annual limitation on cost sharing." 84 Fed. Reg. at 17,544. And, as HHS later explained, prior to this point, "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"—though some states had passed laws on the issue. 85 Fed. Reg. at 29,232; *see also* 84 Fed. Reg. at 17,544 & n.188. HHS then found that "the availability of a coupon may cause physicians and beneficiaries to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available." 84 Fed. Reg. at 17,544. HHS concluded that such assistance "can distort the market and the true costs of drugs" and "can add significant long-term costs to the health care system that may outweigh the short-term benefits of allowing the coupons, and counter-balance issuers' efforts to point enrollees to more cost-effective drugs." *Id.*

Accordingly, HHS promulgated a new regulation that would, for plan years beginning on or after January 1, 2020, "allow issuers and plans to exclude drug manufacturer coupons from counting toward the annual limitation on cost sharing when a medically appropriate generic drug is available," subject to applicable state law. 84 Fed. Reg. at 17,456 (the "2020 NBPP" or "2020 Rule"); *see also id.* at 17,544-46, *codified at* 45 C.F.R. § 156.130(h)(1). As then finalized, 45 C.F.R. § 156.130(h) read as follows:

> § 156.130 Cost-sharing requirements.
>
> . . .
>
> (h) Use of drug manufacturer coupons. For plan years beginning on or after January 1, 2020:
>
> (1) 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).

84 Fed. Reg. at 17,567-68. Essentially, the 2020 Rule expressly permitted the use of copay accumulator programs by insurers, subject to applicable state law—but only with respect to drugs for which a generic alternative was available and medically appropriate. In the rule's preamble, HHS emphasized that "issuers may, but are not required to, undertake the option to exclude manufacturer coupons from counting towards the annual limitation on cost sharing" in those circumstances. *Id.* at 17,546. The preamble also stated that, with respect to drugs for which there was no available and medically appropriate generic equivalent, "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." *Id.* at 17,545.

III. THE 2019 FAQ

Shortly after issuing the 2020 NBPP in April 2019, HHS, along with the Departments of the Treasury and Labor (collectively, "the Departments"), received feedback that there was confusion about whether HHS's new policy meant that manufacturer financial assistance was required to count toward the annual limitation on cost sharing when no generic equivalent was available. FAQs About Affordable Care Act Implementation Part 40, at 1 (Aug. 26, 2019) (AR004319). Stakeholders expressed concern that, if so, such a policy "could create a conflict with certain rules for high deductible health plans (HDHPs) that are intended to allow eligible individuals to establish a health savings account (HSA)." *Id.* at 2 (AR004320).

The Departments recognized that Internal Revenue Service ("IRS") Notice 2004-50 "states that the provision of drug discounts will not disqualify an individual from being an HSA-eligible individual if the individual is responsible for paying the costs of any drugs (taking into

account the discount) until the deductible of the HDHP is satisfied." AR004320; *see* AR004250 (Q&A 9, IRS Notice 2004-50). In other words, this IRS notice "requires an HDHP to disregard drug discounts and other manufacturers' and providers' discounts in determining if the minimum deductible for an HDHP has been satisfied and only allows amounts actually paid by the individual to be taken into account for that purpose." AR004320. The Departments concluded that "[s]uch a requirement could put the issuer or sponsor of an HDHP in the position of complying with either the requirement under the 2020 NBPP Final Rule for limits on cost sharing in the case of a drug manufacturer coupon for a brand name drug with no available or medically appropriate generic equivalent or the IRS rules for minimum deductibles for HDHPs, but potentially being unable to comply with both rules simultaneously." *Id.*

Accordingly, on August 26, 2019, the Departments issued an FAQ to address the questions this possible conflict raised. AR004319-21. In that FAQ, the Departments stated that, HHS intended, in consultation with the Departments of Labor and the Treasury, "to undertake rulemaking in the forthcoming HHS Notice of Benefit and Payment Parameters for 2021" to address the potential conflict. AR004320-21. The Departments further stated that, "[u]ntil the 2021 NBPP is issued and effective, the Departments will not initiate an enforcement action if an issuer of group or individual health insurance coverage or a group health plan 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." AR004321.

IV. THE 2021 NBPP

As previewed in the FAQ, in 2020, HHS made changes to the policy regarding how drug manufacturer financial assistance will affect an enrollee's annual limitation on cost sharing. 85

Fed. Reg. at 29,230-32 (the "2021 NBPP" or "2021 Rule"); *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. 7,088, 7,090 (proposed Feb. 6, 2020). HHS noted that, since finalizing 45 C.F.R. § 156.130(h)(1), it had received feedback indicating "there was confusion about whether [that subsection], as finalized, requires 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." 85 Fed. Reg. at 29,231. HHS further discussed the possible conflict with IRS Notice 2004-50 and the Departments' response in the form of the FAQ issued in August, 2019. *Id.* In addition, HHS reported that "stakeholders raised questions related to certain administrative issues related to how to determine and apply the net amount to the deductible when an individual receives this type of payment." *Id.* at 29,233.

To resolve these problems, HHS decided to revise 45 C.F.R. § 156.130(h) to give plans and issuers "the flexibility, subject to applicable state law, to determine whether to include or exclude amounts of manufacturer support from the annual limitation on cost sharing, regardless of whether a generic equivalent is available." 85 Fed. Reg. at 29,231. Specifically, HHS revised 45 C.F.R. § 156.130(h) to provide that, to the extent consistent with applicable state law, amounts paid using any form of direct manufacturer support, whether or not generic equivalents were available for the drug at issue, "*may be, but are not required to be*, counted toward the annual limitation on cost sharing." *Id*. at 29,230 (emphasis added). The current version of 45 C.F.R. § 156.130(h) now reads as follows:

> § 156.130 Cost-sharing requirements.
>
> . . .

> (h) Use of direct support offered by drug manufacturers. 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.

Essentially, the current rule expressly permits issuers and group health plans to use copay accumulator programs with respect to any drug, whether or not it has a generic equivalent, subject to relevant state law. HHS explained that this current regulation would enable issuers and group health plans "to continue longstanding practices with regard to how and whether drug manufacturer coupons accrue towards an enrollee's annual limitation on cost sharing." 85 Fed. Reg. at 29,231.

Plaintiffs, three individuals and three healthcare advocacy organizations, filed the present suit challenging the 2021 Rule under the APA. HHS served the Administrative Record, and the parties have now filed motions for summary judgment based on that record.[1]

STANDARD OF REVIEW

Defendants seek summary judgment on the grounds either (1) that Plaintiffs' claims are nonjusticiable because they seek review of agency action that is not final, 5 U.S.C. § 704, and is "committed to agency discretion by law," *id.* § 701(a)(2), or (2) that, even if subject to review, the rule at issue is "in accordance with law[,]" and not arbitrary and capricious under the APA. *Id*. § 706(2)(A), (C). "[W]hen a party seeks review of agency action under the APA, the district

[1] Defendants previously moved to dismiss this case for lack of standing (ECF No. 8), and, in response, Plaintiffs filed their First Amended Complaint (ECF No. 10). Defendants do not contest that at least one of the plaintiffs in the FAC, Cynthia Regan, who takes a biologic medication, Humira, that currently has no generic equivalent, has standing and therefore no longer seek dismissal for lack of standing. *See In re Navy Chaplaincy*, 697 F.3d 1171, 1178 (D.C. Cir. 2012) ("[O]nly one plaintiff must have standing" for plaintiffs' claims to survive.); Regan Decl. ¶ 3 (ECF No. 13-4).

judge sits as an appellate tribunal." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). "Summary judgment thus serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006). The district court applies the "appropriate APA standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court." *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743–44 (1985) (quotation omitted). The court must base its decision on the record before the agency and may not consider extra-record evidence. *Hill Dermaceuticals, Inc. v. Food & Drug Admin*., 709 F.3d 44, 47 (D.C. Cir. 2013). Accordingly, the extra-record materials cited by Plaintiffs (*see, e.g*., Pls.' Mem. at vii) should be disregarded.

Questions regarding the justiciability of a case under the APA go to whether the plaintiffs have stated a valid claim under the APA and may be resolved either on a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) or on summary judgment. *Sierra Club v. Jackson*, 648 F.3d 848, 854 (D.C. Cir. 2011) (A plaintiff who challenges agency action committed to agency discretion by law "cannot state a claim under the APA. Therefore, the court has jurisdiction over his case pursuant to [28 U.S.C.] § 1331, but will properly grant a motion to dismiss the complaint for failure to state a claim." (citation omitted)); *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1222–23 (D.C. Cir. 1993) ("[W]hen a district court is reviewing agency action—sitting as an appellate tribunal—the legal questions raised by a 12(b)(6) motion and a motion for summary judgment are the same.").

ARGUMENT

I. HHS'S DECISION TO PERMIT FLEXIBILITY REGARDING TREATMENT OF MANUFACTURER DRUG ASSISTANCE IS NOT JUSTICIABLE

HHS's decision to permit flexibility with regard to whether manufacturer drug assistance must be considered cost sharing by plans and insurers is not justiciable for two reasons. First, HHS's decision is essentially a decision to decline to set rules in this area and therefore does not constitute final agency action subject to review under the APA. Second, and relatedly, HHS's decision as to whether to regulate in this area is not subject to review because it is agency action "committed to agency discretion by law" where there is no meaningful standard by which to judge the agency's exercise of its discretion.

First, the 2021 NBPP does not present "final agency action" subject to review under 5 U.S.C. § 704. An agency action must generally meet two conditions to be considered final and hence subject to review under the APA. *Bennett v. Spear*, 520 U.S. 154, 177 (1997). First, "the action must mark the 'consummation' of the agency's decisionmaking process . . . —it must not be of a merely tentative or interlocutory nature." *Id.* at 178. Second, "the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Id.* Both *Bennett* prongs must be met to make agency action final. *Soundboard Ass'n v. Fed. Trade Comm'n*, 888 F.3d 1261, 1267 (D.C. Cir. 2018). Defendants do not contest that the first requirement is met here.

To meet the second requirement, the relevant legal consequences must be "direct and appreciable." *U.S. Army Corps of Eng'rs v. Hawkes Co.,* 578 U.S. 590, 598 (2016) (quoting *Bennett*, 520 U.S.at 178). Determining those consequences is a "pragmatic" inquiry that requires courts to examine the "concrete consequences" of an agency action. *Sierra Club v. EPA*, 955 F.3d 56, 62-63 (D.C. Cir. 2020) (citations omitted). In general, agency actions meet this

requirement when they impose "obligations, prohibitions or restrictions on regulated entities" or "compel[] action" and expose those entities to the risk of "significant criminal and civil penalties." *Id.* at 63-64.

In the 2021 NBPP, HHS made it clear that the revised rule was intended to provide complete "flexibility" to states and issuers and plans "to determine whether to *include or exclude* dollar amounts of direct support provided by drug manufacturers from the annual limitation on cost sharing." 85 Fed. Reg. at 29,231 (emphasis added). It further emphasized that issuers and plans could "continue longstanding practices" in this regard, *id.*, and that they "need not make changes to how they have historically handled direct drug manufacturer support amounts," *id.* at 29,232. And it stated that it is "not requir[ing] and . . . not directing issuers and group health plans to any specific practice with regards to how these amounts are treated with respect towards accumulators." *Id.* at 29,233.

Therefore, it is abundantly clear that the 2021 Rule, that is, the current version of 45 C.F.R. § 156.130(h), 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. In other words, the revised rule does not require "anyone to do anything." *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014). It does not "present regulated entities with the 'painful choice between costly compliance and the risk of prosecution at an uncertain point in the future'" or "expose any regulated entity to the possibility of an enforcement action or to enhanced fines or penalties." *Sierra Club*, 955 F.3d at 65 (citations omitted). As with the agency "action" at issue in *Racing Enthusiasts and Suppliers Coalition v. Environmental Protection Agency*, 45 F.4th 353, 358 (D.C. Cir. 2022), HHS's rule here "reads less 'like a ukase' than like an explanation of an administrative retreat by an agency that *declined* to adopt a rule that *would* have had

independent legal force." As a result, the rule "does not have sufficiently concrete consequences for the [regulated parties] to satisfy *Bennett*'s second prong." *Id.* (holding that preamble stating that abandoned regulation was "not intended to represent a change in the law or in EPA's policies or practices" was not final agency action); *see also Am. Petroleum Inst. v. EPA*, 216 F.3d 50, 68 (D.C. Cir. 2000) ("A decision by an agency to defer taking action is not a final action reviewable by the court."). It is therefore not subject to review under the APA. *See* 5 U.S.C. § 704.

To be sure, the analysis is somewhat complicated by the fact that the 2021 NBPP revised the 2020 Rule, then located at 45 C.F.R. § 156.130(h)(1), and the earlier rule did on its face require regulated entities to make changes. Abrogation of a rule with final effect could itself constitute final agency action. *See State Farm*, 463 U.S. at 42 ("[A]n agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance."). However, because the 2020 Rule was effectively suspended and never actually enforced, the 2021 Rule did not alter the then-existing landscape when it revised that rule and therefore did not become a "final rule" simply by doing so. Specifically, the 2020 Rule was originally scheduled to apply only for plan years beginning on or after January 1, 2020, but, well before that date, in August 2019, HHS issued a statement that neither it nor the Departments of the Treasury or Labor would initiate any enforcement actions based on the 2020 Rule. AR004321. Therefore, the 2020 Rule had only a nominal existence, *see generally Johnson v. Dist. of Columbia*, 71 F. Supp. 3d 155, 160 (D.D.C. 2014) (holding that, where "statute is moribund or will not be enforced," there is "no dispute susceptible to resolution by a federal court"), and the ultimate revision by the 2021 Rule, to officially enshrine the existing landscape, did not alter any legal obligations.

Second, the 2021 NBPP is also unreviewable as it represents an exercise of HHS's discretion not to regulate in certain situations. Hence, HHS's action is "agency action committed to agency discretion by law" that is unreviewable under the APA. 5 U.S.C. § 701(a)(2). The Supreme Court has explained that under the APA, "even when Congress has not affirmatively precluded judicial oversight, 'review is not to be had if the statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion.'" *Webster v. Doe*, 486 U.S. 592, 599–600 (1988) (quoting *Heckler v. Chaney*, 470 U.S. 821, 830 (1985)). Thus, in *Webster*, the Supreme Court held that statutory language authorizing an agency to fire employees when it "'shall *deem* such termination necessary or advisable . . .' . . . fairly exudes deference" to the agency and so commits the decision to agency discretion. 486 U.S. at 600 (emphasis in original).

Here, the Affordable Care Act commits discretion to the Secretary to regulate in this area. Specifically, the applicable provision granting regulatory authority here provides that "[t]he Secretary shall, as soon as practicable after March 23, 2010, issue" regulations "with respect to . . . such other requirements [under the ACA] as the Secretary determines appropriate." 42 U.S.C. § 18041(a). This language leaves to the Secretary's sole judgment to "determine[]" when it is "appropriate" to issue regulations as to "other requirements." This authority is discretionary in nature because it "provides no relevant 'statutory reference point' for the court other than the decisionmaker's own views of what is . . . 'appropriate.'" *Milk Train, Inc. v. Veneman*, 310 F.3d 747, 751 (D.C. Cir. 2002); *see also Frontier State Bank Okla. City, Okla. v. FDIC*, 702 F.3d 588, 595 (10th Cir. 2012) (statute vesting banking agency with "authority to establish such minimum level of capital for a banking institution as the appropriate Federal banking agency, in its discretion, deems to be necessary or appropriate" committed determination to agency discretion);

People for the Ethical Treatment of Animals, Inc. v. U.S. Dep't of Agric., 7 F. Supp. 3d 1, 14 (D.D.C. 2013) (finding language authorizing "[t]he Secretary . . . to promulgate such rules, regulations, and orders as he may deem necessary in order to effectuate the purposes of this chapter" committed choice not to promulgate plaintiffs' preferred regulations to agency discretion), *aff'd on other grounds*, 797 F.3d 1087 (D.C. Cir. 2015); *Sierra Club v. Jackson*, 724 F. Supp. 2d 33, 40 (D.D.C. 2010) (finding that, where "the language of the statute itself provides that [the agency] must only take such action as is deemed 'necessary,'" "this statute is, indeed, discretionary in nature" because " a determination of what is 'necessary' in any given situation is an inherently varied and speculative inquiry") (citation omitted), *aff'd on other grounds*, 648 F.3d 848. Accordingly, "there is no law to apply" to judge the HHS's exercise of its regulatory discretion here, *Chaney*, 470 U.S. at 834, and the 2021 Rule is not reviewable for this reason as well.

II. HHS'S DECISION TO PERMIT FLEXIBILITY REGARDING TREATMENT OF MANUFACTURER DRUG ASSISTANCE IS CONSISTENT WITH THE STATUTE AND NOT ARBITRARY OR CAPRICIOUS

Even if Plaintiffs could overcome these justiciability hurdles, HHS properly concluded that the relevant statute is ambiguous as to whether the value of manufacturer coupons counts as cost sharing, and HHS's decision to permit flexibility in this area is not arbitrary or capricious. Therefore, Defendants are entitled to summary judgment on Plaintiffs' claims under the APA.

A. HHS Correctly Concluded That the Statutory Definition Is Ambiguous as to Whether the Value of Manufacturer Coupons Counts as Cost Sharing

First, HHS correctly concluded that the relevant statute defining cost sharing for the purposes of the limitations imposed by the Affordable Care Act permits two interpretations and therefore is ambiguous. "Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the

legislative purpose." *Park 'N Fly, Inc. v. Dollar Park & Fly, Inc.*, 469 U.S. 189, 194 (1985). In the present case, 42 U.S.C. § 18022(c)(3)(A) defines "cost-sharing" for the purposes of the annual limitation on cost sharing to include—

> (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.

The definition does not explicitly mention manufacturer financial assistance and thus does not speak directly to whether such financial assistance must be considered "similar" to other cost-sharing amounts or expenditures "required" of an enrollee.

After consideration of the statute and the nature of manufacturer assistance, HHS concluded that the definition of cost sharing could be interpreted to *exclude* the amounts of manufacturer assistance because "the value of the direct drug manufacturer support could be viewed as not representing costs incurred by or charged to enrollees." 85 Fed. Reg. at 29,234; *see also id.* at 7,136. HHS explained that the coupon "could be viewed as representing a reduction . . . in the amount that the enrollee is required to pay at the point of sale in order to obtain the drug." 85 Fed. Reg. at 29,234. As further discussed below, this interpretation is supported by the common understanding of words such as "deductible," "coinsurance," and "copayments," which generally refer to amounts "you pay." *See* Pls.' Mem. 4 nn.1& 2. It is also supported by the cross-reference in subsection 18022(c)(3)(A)(ii) to the definition of qualified medical expenses in 26 U.S.C. § 223(d)(2)(A). That statute defines "qualified medical expenses" as "amounts paid by [a] beneficiary for medical care . . . but only to the extent such amounts are not compensated for by insurance or otherwise." 26 U.S.C. § 223(d)(2)(A).

However, HHS also found it possible to interpret the statute to *include* manufacturer financial assistance amounts as cost sharing based on the reference to "charges." This interpretation is possible because the manufacturer assistance "can be considered part of the overall charges incurred by the enrollee as the consumer cannot obtain the drug without providing the full amount owed," either through cash for the entire amount or through some combination of cash and coupons or other assistance. 85 Fed. Reg. at 29,234. Consistent with this interpretation, it is thus possible to read the "not compensated for by insurance or otherwise" language as applying only to subsection 18022(c)(3)(A)(ii) and not to the distinct and linguistically unrelated subsection (i).

Accordingly, HHS reasonably concluded that the term "cost sharing" was "subject to interpretation," *i.e.*, ambiguous, as to whether manufacturer financial assistance must constitute cost sharing. *Rust v. Sullivan*, 500 U.S. 173, 184 (1991) (holding that statute was ambiguous where the language "does not speak directly to the issues of counseling, referral, advocacy, or program integrity"); *Young v. Cmty. Nutrition Inst.*, 476 U.S. 974, 980 (1986) (finding statute ambiguous where "the phrasing . . . admits of either respondents' or petitioner's reading of the statute"). It certainly does not compel the reading that Plaintiffs advance, namely, that manufacturer financial assistance must be included in cost sharing.

Plaintiffs disagree that the first interpretation of the statute is possible. Rather, they contend that the statute must be interpreted to "sweep[] within the definition of 'cost-sharing' any 'deductibles, coinsurance, copayments, or similar charges' that are 'required of' the insured individual in order to access her healthcare, regardless of whether the individual turns to manufacturer assistance to fulfil that 'require[ment].'" Pls.' Mem. 15. Plaintiffs first posit that the ordinary meanings of "deductibles," "coinsurance," and "copayments," referenced in

subsection (i) of section 18022(c)(3)(A) but undefined there, imply an emphasis on the amount "'charg[ed]' to the patient, not the provenance of the funds ultimately paid to the provider." *Id.* at 14. They also examine the language of subsection (ii) of section 18022, which includes as cost-sharing "any other expenditure required of an insured individual," and, they say, this language means that the clause (i) categories are also types of expenditures "*required of*" an insured individual. *Id.* They argue that this language confirms that "the focus [is] on the legal *responsibility* for payment, not where the insured gets the money to satisfy that responsibility." *Id.* They conclude that section (i) therefore includes all amounts the enrollee was "charg[ed]," including amounts provided by "outside sources in order to fulfil that financial obligation." *Id.*

As stated above, HHS does not disagree that this reading is one possible reading of the statute. However, Plaintiffs' reasoning is puzzlingly inconsistent—earlier in their brief, they cite definitions of deductibles, copayments, and co-insurance that reference only what "you [i.e., the patient] pay." Pls.' Mem. at 4 nn.1 & 2. In any event, the definitional analysis cannot bear the weight Plaintiffs give it. Plaintiffs acknowledge that Black's Law Dictionary defines copayments as amounts "borne by the insured" (*id.* at 14 (emphasis omitted)); *see also* "Insurance," Black's Law Dictionary (11th Ed.) (defining "coinsurance" to mean "[i]nsurance under which the insurer and insured jointly bear responsibility")—but cite nothing to suggest that "bear" in this context has anything to do with "legal responsibility," as proposed by Plaintiffs, rather than who actually pays, as suggested in HHS's alternate read. *Cf.* "Bear," Black's Law Dictionary (11th Ed. 2019) (defining "bear" to mean "[t]o support or carry"). And Plaintiffs' preferred dictionary expressly links "copayment" to the amount patients actually pay: "A fixed amount that *a patient pays* to a healthcare provider according to the terms of the patient's health plan." "Copayment," Black's Law Dictionary (11th Ed. 2019) (emphasis added). These

ambiguous definitions hardly help to illuminate whether the statute intended manufacturer help to count as cost sharing. Indeed, if anything unites them at all, it is that cost sharing is meant to ensure an insured bears some economic burden—has some colloquial "skin in the game"—a fact that could cut different ways depending on circumstance of third party assistance.

To nevertheless exclude the first reading of the statute found by HHS, Plaintiffs examine the remaining language of subsection (ii) of section 18022(c)(3)(A), which further explains that cost-sharing includes "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)." Pls.' Mem. 15 (quoting 42 U.S.C. § 18022(c)(3)(A)(ii)). They turn to 26 U.S.C. § 223(d)(2)(A), which, as quoted above only includes medical expenses to the extent "not compensated for by insurance or otherwise." They contend that this reference to compensation means that clause (ii) of section 18022 "look[s] to whether the beneficiary is 'compensated' for an expense or instead pays it out of pocket." Pls.' Mem. 15. They then argue that, "[u]nder well-settled principles of construction," because clause (i) does not contain the same limitation or a cross-reference to 26 U.S.C. § 223(d)(2), "Congress's choice to include this limitation only in clause (ii) indicates that no such restriction [regarding compensation] is present in clause (i)." *Id.* Thus, Plaintiffs argue, "deductibles, coinsurance, copayments, or similar charges" constitute cost sharing even if they were compensated for by insurance or otherwise.

However, Plaintiffs' analysis makes too many unwarranted assumptions. The limiting language in a tax statute cross-referenced in one subsection of another statute (enacted at a different time) cannot dictate the meaning of another subsection of that latter statute. First, "'negative implications raised by disparate provisions are strongest' in those instances in which the relevant statutory provisions were 'considered simultaneously when the language raising the

implication was inserted.'" *Gomez-Perez v. Potter*, 553 U.S. 474, 486 (2008) (quoting *Lindh v. Murphy*, 521 U.S. 320, 330 (1997)). Here, the statutes at issue were not considered or enacted together and were never made part of the same title of the U.S. Code. Section 223(d)(2) of Title 26 was enacted in 2003 by Public Law No. 108-173. *See* Pub. L. No. 108-173, tit. XII, § 1201, 117 Stat. 2066 (2003). Section 18022 of Title 42 was enacted in 2010 as part of the Affordable Care Act. *See* Pub. L. No. 111-148, tit. I, subtit. D, pt. I, § 1302, 124 Stat. 119, 163 (2010). Thus, the exclusionary presumption that Plaintiffs rely on does not apply here. *See Gomez–Perez*, 553 U.S. at 486 (declining to apply presumption where the "relevant provisions were not considered or enacted together"); *United States v. Harmon*, 474 F. Supp. 3d 76, 93 (D.D.C. 2020) (declining to apply presumption when one statute was enacted by the D.C. Council in 2000, and the second was adopted for D.C. by Congress a decade before home rule, in 1963); *see also GTE S. Inc. v. Morrison*, 6 F. Supp. 2d 517, 530 (E.D. Va. 1998) ("[I]nterpretive inferences should be drawn from different sections in the same Act as opposed to different Acts."), *aff'd*, 199 F.3d 733 (4th Cir. 1999).

Second, the exclusionary presumption on which Plaintiffs rely "is not absolute. Context counts, and it is sometimes difficult to read much into the absence of a word that is present elsewhere in a statute." *Bartenwerfer v. Buckley*, 598 U.S. ---, ---, 143 S. Ct. 665, 673 (2023); *see also Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253 (1992) ("[C]anons of construction are no more than rules of thumb that help courts determine the meaning of legislation."). Thus, the Court must thoroughly examine "other textual pointers" before reaching a conclusion, *Field v. Mans*, 516 U.S. 59, 75 (1995), and the presumption "grows weaker with each difference in the formulation of the provisions under inspection." *City of Columbus v. Ours Garage & Wrecker Serv., Inc.*, 536 U.S. 424, 435 (2002). Only "[t]he more apparently deliberate the contrast, the

stronger the inference." *Field*, 516 U.S. at 75. Here, there is no indication that Congress meant a "deliberate . . . contrast" between subsection (i) and (ii) of section 18022(c)(3)(A) with regard to amounts compensated for by insurance or otherwise. To be sure, there is a facial contrast because only subsection (ii) mentions the other statute that itself mentions compensation. However, the entirely different language in the two provisions does not support the conclusion that the contrast was "deliberate" as it pertains to amounts compensated for by insurance or otherwise and counsels against trying to read the absence of language in subsection (i) as probative. *See Nat'l Postal Pol'y Council v. Postal Regul. Comm'n*, 17 F.4th 1184, 1191 (D.C. Cir. 2021) (holding that exclusionary presumption had "limited force" where "the two provisions use different words and are not otherwise parallel"), *cert. denied*, 142 S. Ct. 2868 (2022). In fact, another rule of statutory construction, that "[a] specific provision" "controls one[s] of more general application," *Bloate v. United States*, 559 U.S. 196, 207 (2010) (citation omitted), argues for the view that both subsections could be limited to expenses that are "not compensated for by insurance or otherwise."

Third, Plaintiffs' interpretation is not internally consistent for an additional reason other than those discussed above. While arguing that the statutory text requires that all manufacturer assistance be considered part of cost sharing, *see* Pls.' Mem. 15, they seek only to have the agency set aside the 2021 Rule. FAC ¶¶ 88-100 & Prayer for Relief. This action would leave in place the 2020 Rule, which permits plans and issuers to exclude manufacturer assistance from cost sharing for drugs that have generic equivalents. Although Plaintiffs acknowledge that the agency found that copay accumulator adjustment programs serve "a socially beneficial economic purpose" when applied in the case of generic equivalents (Pls.' Mem. at 34), they do not explain

how this interpretation is consistent with their inflexible interpretation of the statutory (or regulatory) language.

Thus, the reference to "amounts not compensated by insurance or otherwise" that can be read into subsection (ii) should not be interpreted to exclude compensation by insurance or otherwise as a factor in determining what constitutes cost sharing under subsection (i) and HHS reasonably concluded that the statutory reference to "deductibles, coinsurance, copayments, or similar charges" was ambiguous when applied to manufacturer assistance.

B. HHS's Decision to Permit Flexibility Is Not Arbitrary or Capricious

Given the ambiguity in the statute, the question for the Court now is whether HHS's decision not to resolve that ambiguity is reasonable and reasonably explained.[2] For the reasons set forth below, HHS considered the "relevant factors," made "rational" decisions on how to proceed, and "articulate[d] a satisfactory explanation for its action." *State Farm*, 463 U.S. at 43. Plaintiffs' arguments to the contrary are without merit. Accordingly, the rule should be upheld.

1. HHS's decision does not conflict with the regulatory definition of cost sharing

Plaintiffs first argue that the 2021 Rule is arbitrary and capricious because it "clashes" with HHS's own regulatory definition of cost sharing. Pls.' Mem. 18. HHS concluded that the regulation was ambiguous for the same reasons that it concluded the statute was ambiguous. 85

[2] Defendants agree with Plaintiffs (Pls.' Mem. 17) that *Chevron* step 2 deference does not come into play here because HHS has not exercised its discretion to adopt an interpretation of the statute. *See Chevron USA, Inc. v. Nat. Res. Def. Council*, 467 U.S. 837, 842-45 (1984). Therefore, to the extent the decision at issue is reviewable (and Defendants contend it is not), this case is governed by the "arbitrary and capricious" standard set out in *State Farm*, not *Chevron's* deference standard. *See State Farm*, 463 U.S. at 42 (stating that, under arbitrary and capricious review, a reviewing court may not set aside agency action "that is rational, based on consideration of the relevant factors and within the scope of the authority delegated to the agency by the statute"); *Stilwell v. Off. of Thrift Supervision*, 569 F.3d 514, 519 (D.C. Cir. 2009) (upholding agency rule "so long as it is reasonable and reasonably explained").

Fed. Reg. at 29,234. The Court applies the same "traditional tools" in interpreting the language of the regulation as it applies in interpreting the language of the statute. *Kisor v. Wilkie*, --- U.S. ---, ---, 139 S. Ct. 2400, 2415 (2019) ("[B]efore concluding that a rule is genuinely ambiguous, a court must exhaust all the 'traditional tools' of construction.") (citing *Chevron*, 467 U.S. at 843 n.9). Here, as in the statute, the regulatory definition does not specifically address manufacturer assistance and contains language similar to that in the statute ("expenditure required by or on behalf of") that could be interpreted either way. Therefore, HHS's conclusion that the regulation is ambiguous should be upheld for the same reason that the Court should uphold its conclusion about the statutory ambiguity.

Specifically, the regulatory definition provides that:

> 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. As with the statute, HHS concluded that this regulation was ambiguous because, on the one hand, "[t]he value of the direct drug manufacturer support can be considered part of the overall charges incurred by the enrollee as the consumer cannot obtain the drug without providing the full amount owed." 85 Fed. Reg. at 29,234. On the other hand, "the value of the direct drug manufacturer support could be viewed as not representing costs incurred by or charged to enrollees" but could instead "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." *Id.*

To be sure, the regulatory definition, unlike the statute, adds the phrase "on behalf of" an enrollee. Plaintiffs argue that the regulatory definition must accordingly be read to include

manufacturer assistance within cost sharing because that assistance constitutes "expenditures" "unassailably made 'on behalf of' the patient beneficiary, even though they do not come out of the patient's own pocket." Pls.' Mem. 19. However, HHS reasonably concluded that manufacturer assistance could also "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." 85 Fed. Reg. at 29,234 (emphasis added). On that view, the regulation pierces through the way a drug manufacturer structures a price discount to measure its actual economic impact, which is that the drug manufacturer, on net, receives less for the drug. By asking the court to prioritize the financial engineering behind certain discounts, Plaintiffs ignore the focus on actual economic effects that unite the various cost sharing definitions discussed above. Thus, Plaintiffs' interpretation ignores the ambiguities and/or different views of the way manufacturer assistance operates and should be rejected.

2. HHS's decision is reasonable even though it allows different states and insurers or plans to choose different policies

HHS's decision not to resolve the ambiguity in the statute and regulation is not arbitrary and capricious simply because it allows states and issuers or plans to set different rules in this regard, as Plaintiffs contend (Pls.' Mem. 20-21). "Agencies are permitted to promulgate regulations interpreting ambiguous statutes without having to resolve *all* possible ambiguity." *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 34 (D.C. Cir. 2019) (emphasis in original) (rejecting argument that regulation that left statutory ambiguity unresolved was arbitrary and capricious). After all, "[a]n agency has some leeway reasonably to resolve uncertainty, as a policy matter, in favor of more regulation or less." *Ctr. for Auto Safety v. Fed. Highway Admin.*, 956 F.2d 309, 316 (D.C. Cir. 1992) (Thomas, J.).

This is particularly true in the health insurance context where states, and issuers and plans within states, do not have uniform rules or provisions. Although federal law, and in particular, the Affordable Care Act, sets numerous uniformly applicable standards for health policies or plans, states have also historically and permissibly regulated in this area. *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 744 (1985) (noting various federal laws that "reserve[e] . . . the business of insurance to the States"). As a result, different rules for health insurance policies or plans may apply in different states and, consistent with applicable federal and state laws, different plans and issuers may choose different provisions for their coverage, thus affording consumers choices depending on their coverage needs, financial situation, and other considerations. The 2021 Rule merely extends this provision of choice to the question of whether to count manufacturer financial assistance as cost sharing.

This commonplace variety in insurance policies or plans does not mean that HHS's 2021 Rule is arbitrary because it allows "regulated parties . . . to decide, on a case by case basis, whether a duly promulgated law applies to them," as Plaintiffs assert. Pls' Mem. 21. First, states, to which the HHS Rule primarily defers, are not regulated parties in this regard. States may set their own rules for how health plans treat manufacturer assistance. *See, e.g.*, 85 Fed. Reg. at 17,544; AR000442; AR002673. Second, states and issuers and plans continue to be subject to all laws regarding limits on cost sharing. HHS has simply declined to step in and resolve statutory ambiguities as the issue continues to percolate among the states. And, to ensure that consistency prevails between truly similarly situated individuals, in promulgating the rule, HHS emphasized to issuers "that when determining if and how to factor in direct drug manufacturer support amounts towards the annual limitation on cost sharing, such policies must apply in a uniform, non-discriminatory manner." 85 Fed. Reg. at 29,232-33.

3. HHS reasonably explained the change from the 2020 Rule, which had not engendered any reliance interests

When an agency departs from a prior policy, it must "display awareness that it *is* changing position" and it "must show that there are good reasons for the new policy." *FCC v. Fox Television Stations, Inc*., 556 U.S. 502, 515 (2009) (emphasis in original). But it need not establish "that the reasons for the new policy are *better* than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better, which the conscious change of course adequately indicates." *Id*. (emphasis in original).

Here, HHS displayed an awareness that it was changing policy from the 2020 Rule and reasonably explained the bases for its decision to permit flexibility with regard to whether manufacturer assistance constituted cost sharing. First, HHS highlighted the administrative difficulties posed by the 2020 Rule, noting that "stakeholders raised questions related to certain administrative issues related to how to determine and apply the net amount to the deductible when an individual receives this type of payment." 85 Fed. Reg. at 29,233; *see, e.g.,* AR002270 (comment by America's Health Insurance Plans that health insurance providers are "unable to identify all coupons" because in many cases they "are unaware when drug manufacturer assistance is provided and drug manufacturers change the parameters of assistance programs to conceal this assistance"); AR002637 (comment by Pharmaceutical Care Management Association that a pharmacy benefit manager "is generally not aware of the use of manufacturer direct assistance at the point-of-sale"); AR002659 (comment by Anthem that "[c]urrently group health plans and issuers often do not have the information necessary to monitor the use of drug manufacturer coupons"); AR002788 (report by National Council for Prescription Drug Programs stating that "[t]here is currently no standard mechanism to share transaction data between

prescription assistance programs and commercial health insurance programs" and then discussing various reporting options).

Second, HHS cited the possible conflict between the 2020 Rule and the IRS guidance regarding health savings accounts ("HSAs") associated with high deductible health plans ("HDHPs"). That guidance stated that the provision of discounts for healthcare services or products will not disqualify an individual from being eligible for an HSA "if the individual is responsible for paying the costs of the health care (taking into account the discount) until the deductible of the HDHP is satisfied." AR004250. Therefore, HHS, along with the Departments of Treasury and Labor, concluded that an issuer or sponsor of an HDHP could, in a case where an enrollee received manufacturer assistance for a brand name drug with no suitable generic equivalent, be put in the position of complying with either the requirement under the 2020 Rule for limits on cost sharing or the IRS rules for minimum deductibles for HDHPs coupled with an HSA, but potentially being unable to comply with both rules simultaneously. AR004320. Accordingly, HHS adopted the 2021 Rule to provide maximum flexibility and allow issuers to avoid this type of conflict for those situations where it may arise. *Id.*

HHS's acknowledgement that commenters identified a possible conflict between the IRS rules and HHS's 2020 Rule is a "good reason[]" (*Fox*, 556 U.S. at 515) for its decision to change its policy to one of flexibility. Moreover, it fully acknowledged that it was changing position from the 2020 Rule. 85 Fed. Reg. at 29,230-31. HHS acknowledged that the IRS guidance might not be directly applicable to drug manufacturer assistance, as Plaintiffs argue (Pls.' Mem. 23-25), but reasonably concluded that it would be consistent with IRS's guidance for it to apply the same rule to such assistance. 85 Fed. Reg. at 29,233. HHS's wish to avoid this potential conflict is sufficient to justify its decision to change its policy.

Under *Fox*, an agency is free to change a policy decision as long as "the new policy is permissible under the statute, . . . there are good reasons for it, and . . . the agency believes it to be better." *Fox*, 556 U.S. at 515 (emphasis omitted). HHS did not, and was not required, as Plaintiffs imply, to find that the IRS rule directly conflicted with the 2020 Rule or to delve into the sources or correctness of the IRS's interpretation. Notably, Plaintiffs themselves have not challenged the IRS guidance itself, only whether it might be interpreted to extend to the situation at issue here. It suffices that HHS felt that, as a matter of policy, it preferred not to require issuers and plans to follow a course that created a potential conflict but rather wished "to provide maximum flexibility and allow issuers to avoid this type of conflict for those situations where it may arise." 85 Fed. Reg. at 29,233. "An initial agency interpretation is not instantly carved in stone. On the contrary, the agency . . . must consider varying interpretations and the wisdom of its policy on a continuing basis." *Chevron*, 467 U.S. at 863-64; *see also Nat'l Home Equity Mortg. Ass'n v. Off. of Thrift Supervision*, 373 F.3d 1355, 1360 (D.C. Cir. 2004) (agency reasonably returned to original policy "in response to what it reasonably perceived as the unanticipated and undesirable fallout from the change it made").

Plaintiffs argue that HHS has nevertheless not complied with *Fox*'s requirements because it has not attempted "to distinguish or rebut [its] prior factual finding that accumulators are justified by market forces only 'when a less expensive and equally effective generic *is* available.'" Pls.' Mem. at 33. But Plaintiffs ignore that HHS did directly address its prior finding, reiterating its continuing concern with "the market distortion effects related to drug manufacturer support amounts when consumers select a higher-cost brand name drug over an equally effective, medical appropriate generic drug." 85 Fed. Reg. at 29,233. HHS acknowledged that that finding was still accurate and that it would still be beneficial to

encourage generic drug use, but decided, permissibly and reasonably, that the better course was to defer to states and plans and issuers as to how best to address the market distortions. Moreover, HHS stated that the flexibility it was permitting by the new policy "would also afford issuers [and plans] the same opportunity as under the current § 156.130(h)(1) to incentivize generic drug usage by excluding the amounts of direct drug manufacturer support for brand name drugs from the annual limitation on cost sharing when a medically appropriate generic equivalent is available." *Id.* at 29,231. It further stated that it "continue[d] to encourage issuers to find innovative methods to address the market distortion that occurs when consumers select a higher-cost brand name drug over an equally effective, medically appropriate generic drug," *id.* at 29,232, and that it "encourage[d] issuers and group health plans to consider the flexibility to exclude these amounts from the annual limitation on cost sharing" to address these concerns. *Id.* at 29,234.

An agency may change its course "either with or without a change in circumstances," *State Farm*, 463 U.S. at 57 (citation omitted), if it "*believes* [the new course] to be better." *Fox*, 556 U.S. at 515. In such circumstances, "the agency need not always provide a more detailed justification than what would suffice for a new policy created on a blank slate," and the Court's review is not "more searching" than its review of the original action. *Id*. at 514-15. Here, "[r]ather than ignoring its prior findings, [HHS] changed its balancing of the relevant incentives," which was within its discretion to do. *Mozilla Corp. v. FCC*, 940 F.3d 1, 56 (D.C. Cir. 2019); *see also Am. Hosp. Ass'n v. Azar*, 983 F.3d 528, 539–40 (D.C. Cir. 2020) (holding that HHS rule satisfied *Fox* where the "rule expressly acknowledges the prior policy. . . [and] then gives 'good reasons' for requiring more").

Accordingly, HHS's change of position is permissible notwithstanding the unchanged concern with market distortion, which it, on reconsideration, felt was best addressed by states or by plans or issuers in potentially more innovative ways. *See* AR001187 (comment by the Coalition for Affordable Drugs discussing that plan sponsors and pharmacy benefit managers are using tools to encourage not only medically-equivalent drugs but "biosimilar drugs, and therapeutically equivalent brand drugs"); AR002272 (comment by America's Health Insurance Plans stating that "[c]ompetition between brand drugs . . . can and should drive down the cost of many brand name drugs that do not have generic equivalents"); AR004199 (recommending that HHS "empower health insurance providers to address coupons in new ways as they identify ways to do so"). As discussed, the market was already responding to try to work out the market distortions introduced by drug manufacturer assistance when HHS first proposed intervening. *See supra* at 3-5. Plaintiffs' request that the Court invalidate the agency's ultimate decision to wait and see if private parties and the states can solve the market distortion problem before finalizing federal regulatory intervention conflicts with longstanding D.C. Circuit precedent. *See WWHT, Inc. v. FCC*, 656 F.2d 807, 817 (D.C. Cir. 1981) ("Further, even if an agency considers a particular problem worthy of regulation, it may determine for reasons lying within its special expertise that the time for action has not yet arrived. . . . The circumstances in the regulated industry may be evolving in a way that could vitiate the need for regulation . . . ." (internal quotations and citations omitted)).

Plaintiffs also argue that HHS did not adequately take into account "reliance interests that may have accreted around its prior policy." Pls.' Mem. 34. But any such reliance interests could not have been significant, given that the Departments effectively suspended any enforcement of the prior policy (the 2020 Rule) before it took effect. An agency need only "be cognizant that

longstanding policies may have 'engendered serious reliance interests that must be taken into account,'" *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222, (2016) (emphasis supplied, citation omitted), and the 2020 Rule, which was never enforced, was not such a longstanding policy at the time the 2021 Rule was finalized. *See Calixto v. Walsh*, No. CV 19-1853 (CKK), 2022 WL 4446383, at *16 (D.D.C. Sept. 23, 2022) (no longstanding policy where determinations that were "properly challenged" never "became final"); *Gentiva Health Servs., Inc. v. Cochran*, 523 F. Supp. 3d 81, 99 (D.D.C. 2021) (no "longstanding policy" where "the original approach was neither final nor embodied in any official agency action or policy"), *aff'd*, 31 F.4th 766 (D.C. Cir. 2022). *Cf. Encino Motorcars*, 579 U.S. at 222 (holding that agency had duty to address "decades of industry reliance on the [agency's] prior policy").

Moreover, although the evidence Plaintiffs cite shows potential harm from the 2021 Rule itself, it does not show harm caused by decisions made *as a result of reliance* on the 2020 Rule. Plaintiffs cite comments which, they claim, show that "patients may have started on chronic medications with the help of manufacturer copay assistance, only to be undercut by the agencies' approval of copay accumulators even when no generic assistance is available." Pls.' Mem. 34-35. But those comments do not state that plans or issuers initially chose not to apply copay accumulators in those circumstances *as a result of* the (suspended) 2020 Rule. *Cf.* AR001267 (comment by the Pulmonary Hypertension Association reporting that one issuer that *had* initially made a change to comply with the 2020 Rule "revert[ed]" to its prior policy after HHS issued its August 2019 notice). Nor do the comments show any patients have been harmed as a result of potentially having to change drug regimes begun during the pendency of the (effectively suspended) 2020 Rule. In other words, while it certainly is true that institution of copay accumulator programs for drugs without available generic substitutes will adversely affect some

individuals, there is no evidence that those individuals (or their issuers or plans) relied detrimentally on the 202 Rule. *See Amalgamated Transit Union, Int'l v. U.S. Dep't of Labor*, No. 2:20-CV-00953-KJM-DB, 2022 WL 17978627, at *20 (E.D. Cal. Dec. 28, 2022) (stressing importance of reliance interests where individuals "made consequential, long-lasting decisions they could not easily reverse, in reliance on a federal authority's discretionary policy choices"); *cf. Council of Parent Att'ys & Advocs., Inc. v. DeVos*, 365 F. Supp. 3d 28, 54 (D.D.C. 2019) (identifying as reliance costs those costs incurred to come into compliance with the regulation at issue). And, of course, as HHS was merely continuing the policy of flexibility that pre-dated the 2020 Rule, it could not have disrupted any reliance interests that were based on the pre-2020 landscape. *See, e.g.*, AR003728 (comment of Pharmaceutical Care Management Association that a third of employer health plans used copay accumulators).

4. HHS reasonably assessed the potential costs to patients

Plaintiffs also contend that HHS acted arbitrarily and capriciously in concluding that the impact of the 2021 Rule on patients' out-of-pocket costs would be limited. Pls.' Mem. 29-32. Plaintiffs claim that HHS's conclusion "runs contrary to basic economic realities," which, in their view, dictate that issuers and plans will implement copay accumulator programs across-the-board to capture additional profits and to remain viable in a competitive marketplace. *Id.* at 30.

The Court reviews an agency's "cost-benefit analysis deferentially." *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012); *see also Off. of Commc'n of United Church of Christ v. FCC*, 707 F.2d 1413, 1440 (D.C. Cir. 1983) ("[C]ost-benefit analyses epitomize the types of decisions that are most appropriately entrusted to the expertise of an agency.") "[I]n view of the complex nature of economic analysis typical in the regulation promulgation process, [the] burden to show error is high." *Nat'l Ass'n of Home Builders*, 682

F.3d at 1040 (citation omitted). The Court should not "undertake its own economic study, but must uphold the regulations if [the agency] has established in the record a reasonable basis for its decision." *Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 563 (D.C. Cir. 2002) (citation omitted).

Here, there is sufficient evidence to reasonably support HHS's conclusion. Up through the 2019 plan year, HHS had not regulated the use of copay accumulator programs, and therefore plans or issuers were free to adopt them, unless prohibited by otherwise applicable law. However, not all had done so. Plans and issuers were also free to choose their own course in 2020 because HHS had effectively suspended enforcement of the 2020 Rule. Therefore, at the time the 2021 Rule was promulgated, the flexibility that it codified had been the norm for issuers and plans for years. Given the longstanding existence of this flexibility, therefore, HHS reasonably believed that insurers and plans would not make immediate changes to how they historically handled direct drug manufacturer support amounts in response to the 2021 Rule. 85 Fed. Reg. at 29,232 (emphasizing longstanding nature of issuers' and plans' practices); *id.* at 29,253 (same and discussing suspension of 2020 Rule). This conclusion is not arbitrary and capricious in light of the foregoing history. *See Fla. Health Scis. Ctr., Inc. v. Becerra*, No. CV 19-3487 (RC), 2021 WL 2823104, at *9 (D.D.C. July 7, 2021) ("[T]he agency's statement that the . . . Rule 'was consistent with [HHS's] longstanding policy' and consequently would have limited 'additional savings or costs' . . . was not so false that a reasonable mind would be required to reject the conclusion reached."); *see also Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.*, 374 F.3d 1251, 1260–61 (D.C. Cir. 2004) ("Predictions regarding the actions of regulated entities are precisely the type of policy judgments that courts routinely and quite correctly leave to administrative agencies." (citation omitted)).

To be sure, there was also evidence to indicate that some issuers and plans might increase their use of copay accumulator programs even though, as HHS noted, none indicated an intent to do so in comments to the agency. *See* Pls.' Mem. 30-31; 85 Fed. Reg. at 29,232 n.150. HHS recognized this evidence, acknowledging that "some issuers and group health plans may make changes to their plan designed to exclude direct manufacturer support amounts from the annual limitation on cost sharing" and that, as a result, some consumers "may see changes to their plan design … which may increase or decrease their out of pocket costs." 85 Fed. Reg. at 29,232. However, the economic analysis is more complicated than just measuring the immediate impact of an accumulator adjustment program on an individual patient's direct out-of-pocket expenditures; it must take into account health outcomes and the effect on drug prices, as well as other factors.[3] HHS reasonably concluded that, as a result, "[g]iven the multitude of variables and considerations that are out of HHS's control," it "cannot project this burden [on patients] with sufficient certainty." *Id.* HHS further noted that it "intend[s] to continue to monitor the impact of [manufacturer drug] support." *Id.* HHS's analysis of the possible effects on consumers, and its decision to decline to set a definite rule in this area but to continue to monitor the situation is reasonable and does not warrant overturning the 2021 Rule.

[3] *See, e.g.*, AR001287 (comments by the American Diabetes Association "recogniz[ing] that cost-sharing coupons are not a long-term solution to prescription drug affordability issues"); AR002584 (comment by UCB that "[a]ny [s]avings in [p]rescription [d]rug [c]osts [from the use of accumulator adjustment programs] [w]ill [b]e offset by [i]ncreased [o]verall [h]ealthcare [c]osts"); AR002689 (comment by Academy of Managed Care Pharmacy that "[m]anufacturer coupons and other forms of financial assistance programs . . . [p]erhaps counterintuitively, . . . raise the risk of increased overall costs for patients"); AR002325 (comment by Amgen that "reducing patients' financial exposure to cost-sharing," by allowing them to use coupons for expensive drugs, may "reduc[e] unnecessary costs to the health care system"); AR002695 (comment by American Autoimmune Related Diseases Association that copay assistance "facilitate[s] the ability to maintain stability in [a patient's] health conditions, avoid[s] exacerbations or relapses, and achieve[s] continuity of care, [which,] in turn reduce[s] overall health care expenditures").

5. HHS was not required to consider the alternative proposed by Plaintiffs and reasonably decided not to address other forms of patient assistance

Plaintiffs argue that HHS erred in failing to consider one "obvious" alternative, "permit plans to utilize copay accumulator programs only with respect to patients who actually present the supposed conflict—those 'enrolled in an HDHP coupled with an HSA.'" Pls.' Mem. 29. But neither Plaintiffs nor any other commenter raised this alternative during the rulemaking, and "issues not raised in comments before the agency are waived and th[e courts] will not consider them." *Nat'l Wildlife Fed'n*, 286 F.3d at 562 (rejecting contentions that "neither [petitioner] nor any other party before the agency raised. . . during the administrative phase of the rulemaking process"); *see also State Farm*, 463 U.S. at 51 (a rulemaking cannot be found wanting simply because an agency fails to address every alternative "thought conceivable by the mind of man") (quoting *Vermont Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc*., 435 U.S. 519, 551 (1978)); *Koretoff v. Vilsack*, 707 F.3d 394, 398 (D.C. Cir. 2013) (argument that the "Secretary never determined that the treatment rule is 'the only practical means of advancing the interests of the producers'" as required by statute was waived because "the Secretary never considered whether an 'only practical means' determination was necessary for one simple reason: no one suggested during the rulemaking that such a determination was required"). Nor would considering that alternative even have made sense, since, as discussed above, the three Departments did not find a direct conflict with HDHP guidance requiring an exemption—just a potential one.

Finally, in promulgating the 2021 Rule, HHS received comments that the rule "singles out direct drug manufacturer support" and does not address "other forms of patient assistance . . . beyond direct drug manufacturer support, such as crowdfunding amounts, durable medical equipment (DME) manufacturer support, and waived medical debt." 85 Fed. Reg. at 29,234. In

addressing these comments, HHS reiterated its finding that "the availability of a coupon or other direct support may cause physicians and enrollees to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available" and further noted that it had "no evidence that the other types of support identified by the commenter . . . ha[ve] similar distortive effects on the market." *Id.* Accordingly, HHS stated that it "did not propose and [is] not finalizing cost sharing policies regarding such amounts, but will monitor them and their potential impact on the market for potential future rulemaking." *Id.*

Plaintiffs contend that, as a matter of statutory and regulatory interpretation, "there is no basis . . . to conclude that amounts paid using these other forms of third-party support *are* 'cost sharing,' while amounts paid using manufacturer support are not." Pls.' Mem. 36-37. However, since for the reasons set forth above, Plaintiffs' interpretation that manufacturer assistance must be included within the statutory and regulatory definitions of cost sharing is not compelled by the language, neither is their interpretation that other types of financial assistance (crowdfunding amounts, etc.) must be included as cost sharing as well. And while not the subject of this rule, there may be good reason for distinguishing between assistance from drug manufacturers and assistance from other parties. Unlike drug manufacturers, other parties may not set drug prices and so their assistance may be less amenable to being viewed as a "reduction . . . in the amount that the enrollee is required to pay at the point of sale." 85 Fed. Reg. at 29,234.

Plaintiffs also suggest that, since HHS did not find that manufacturer support for drugs without generic alternatives has a distortive effect, it should have treated that support similarly to other forms of third-party assistance, and not similarly to manufacturer support for drugs *with* generic alternatives. Pls.' Mem. 37-38. However, Plaintiffs ignore the actual effect of HHS's rule here. The rule provides complete flexibility to states, plans, and issuers to decide whether

and under what circumstances to exclude manufacturer support amounts from cost sharing. The rule does not *mandate*, as Plaintiffs imply, that such amounts be treated the same regardless of whether a generic alternative is available; rather, it leaves that choice up to states, plans, and issuers. HHS acknowledged that the market-distorting effects are present when generic alternatives are available but chose to "encourage issuers to find innovative methods to address the market distortion that occurs when consumers select a higher-cost brand name drug over an equally effective, medically appropriate generic drug" rather than to set mandatory rules in this area. 85 Fed. Reg. at 29,232. The rule also permits states, plans, and issuers to have similar flexibility with regard to other forms of patient assistance. *Id.* at 29,235. Thus, all forms of assistance are, for the time being, treated the same under HHS's regulations.

In any event, it is permissible for HHS to address one aspect of the problem of third-party support at a time. "'Nothing prohibits federal agencies from moving in an incremental manner,' *Fox*, 556 U.S. at 522 . . . , even when that includes revisiting prior judgments, [*Nat'l Cable & Telecommc'ns Ass'n v. Brand X Internet Servs*., 545 U.S. 967, 1002 (2005)]." *Anna Jacques Hosp. v. Burwell*, 797 F.3d 1155, 1170 (D.C. Cir. 2015). "Agencies, like legislatures, do not generally resolve massive problems in one fell regulatory swoop . . . . They instead whittle away at them over time, refining their preferred approach as circumstances change and as they develop a more nuanced understanding of how best to proceed." *Massachusetts v. EPA*, 549 U.S. 497, 524 (2007) (citation omitted); *Nat'l Ass'n of Broadcasters v. FCC*, 740 F.2d 1190, 1207 (D.C. Cir. 1984) ("[A]gencies . . . need not deal in one fell swoop with the entire breadth of a novel development; instead, 'reform may take place one step at a time, addressing itself to the phase of the problem which seems most acute to the [regulatory] mind.'" (citation omitted)).

III. SHOULD THE COURT DISAGREE, IT SHOULD REMAND THE CASE TO THE AGENCY FOR FURTHER RULEMAKING

If the Court agrees that the statute is ambiguous but concludes that the agency's rule is nevertheless arbitrary and capricious, it should remand to the agency for further rulemaking, rather than attempting to arrive at its own interpretation. "[I]t 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. *PDK Labs., Inc. v. DEA*, 362 F.3d 786, 798 (D.C. Cir. 2004) (quoting *Alarm Indus. Commc'ns Comm. v. FCC*, 131 F.3d 1066, 1072 (D.C. Cir. 1997)). When a statute is ambiguous, Congress has left the gap for the agency to fill, and "the court does not simply impose its own construction on the statute." *Chevron*, 467 U.S. at 84. The courts "therefore generally remand for an agency to make the first interpretation of an ambiguous statutory term when it has failed to do so previously." *Teva Pharms. USA, Inc. v. U.S. Food & Drug Admin*, 182 F.3d 1003, 1007 (D.C. Cir. 1999). HHS should be given the chance "to 'bring its experience and expertise to bear in light of competing interests at stake' and make a reasonable policy choice." *PDK Labs*., 362 F.3d at 797–98.

CONCLUSION

For the foregoing reasons, Defendants are entitled to summary judgment as a matter of law.

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