

**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-2604 (JDB)

**DEFENDANTS' REPLY IN FURTHER SUPPORT OF THEIR CONDITIONAL
MOTION TO CLARIFY SCOPE OF COURT'S ORDER**

Defendants presented their conditional motion to clarify the scope of the Court's September 29, 2023, memorandum opinion and order (ECF Nos. 41 & 42) to explain that they intended to address, through rulemaking, the issues left open by the Court's opinion, including whether financial assistance provided to patients by drug manufacturers qualifies as "cost sharing" under the Affordable Care Act. Defendants also represented that, pending the issuance of a new final rule, the United States Department of Health and Human Services ("HHS") did not intend to take any enforcement action against issuers or plans based on their treatment of such manufacturer assistance. Defendants noted that, although the Court vacated the relevant portion of the 2021 Notice of Benefit and Payment Parameters, it did not order HHS to take any enforcement action.

In their Response to the Government's Motion for Clarification ("Pls.' Resp.") (ECF No. 47), Plaintiffs contend that an order requiring Defendants to enforce the prior regulation is

implicit in this Court’s judgment and that, to make this consequence clear in light of Defendants’ motion, the Court should consider “injunctive relief” directing the agency not to take a non-enforcement stance pending further rulemaking. Defendants respectfully disagree with Plaintiffs’ reading of the Court’s judgment and with their proposed injunction. An order directing an agency to take enforcement action pending a new rulemaking would be extraordinary under any circumstances. *See Heckler v. Chaney*, 470 U.S. 821, 831 (1985) (“[A]n agency’s decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency’s absolute discretion.”); *Cobell v. Norton*, 392 F.3d 461, 476 (D.C. Cir. 2004) (stating that court “may not prescribe the specific steps the government must take to comply with [its] obligations unless it has found that government actions (or inactions) breached a legal duty and that the steps ordered by the court constituted an essential remedy”). As the Court properly did here, “[w]hen a district court reverses agency action and determines that the agency acted unlawfully, ordinarily the appropriate course is simply to identify a legal error and then remand to the agency, because the role of the district court in such situations is to act as an appellate tribunal.” *N. Air Cargo v. Postal Serv.*, 674 F.3d 852, 861 (D.C. Cir. 2012) (citing *PPG Indus., Inc. v. United States*, 52 F.3d 363, 365 (D.C. Cir. 1995)). This is particularly true where, as here, health plans for 2024 are already being offered to consumers based on a regulatory regime finalized months ago. *See Patient Protection and Affordable Care Act*, HHS Notice of Benefit and Payment Parameters for 2024, 88 Fed. Reg. 25,740 (2023). Indeed, to order the agency to take specific actions is reversible error. *See Cty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1011 (D.C. Cir. 1999) (noting that district court erred when it “devise[d] a specific remedy for the Secretary to follow”). An order directing the agency to enforce the prior rule would be especially unwarranted here where the subjects of any

hypothetical future enforcement actions—employer-sponsored plans or insurance companies—are not parties to this case.

In the alternative, if this Court intended to compel HHS to take enforcement action, Defendants ask that the Court address with specificity the enforcement action(s) that HHS is required to take. *See* Fed. R. Civ. P. 65(d)(1)(C). Defendants suggest that, in view of the fact that the Court’s judgment is now on appeal, the Court may do so through an indicative ruling pursuant to Federal Rule of Civil Procedure 62.1. *See also* Pls.’ Resp., at 3 n.1.

Dated: December 18, 2023

Respectfully submitted,

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