

**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' CONDITIONAL MOTION TO CLARIFY SCOPE OF COURT'S
ORDER**

Defendants respectfully present this conditional motion to clarify the scope of the Court's September 29, 2023, memorandum opinion and order (ECF Nos. 41 & 42) in this case.

Plaintiffs in this case challenged a rule issued by the United States Department of Health and Human Services ("HHS"). The rule permitted, but did not require, health insurance issuers and group health plans to decline to credit certain financial assistance provided to patients by drug manufacturers when calculating whether those patients had 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"). In a September 29, 2023, memorandum opinion and order, this Court held that the 2021 NBPP is unlawful "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.” ECF No. 42, at 2. The Court “vacate[d] the 2021 NBPP to the extent that it amends 42 C.F.R. § 156.130(h),” and remanded the matter “to permit the agencies to interpret the statutory definition [of cost sharing] in the first instance.” *Id.* at 20, 25 n.5.

HHS intends 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. Pending the issuance of a new final rule, HHS does not intend to take any enforcement action against issuers or plans based on their treatment of such manufacturer assistance. Defendants do not understand this Court’s order to require HHS to take enforcement action. The Court vacated the relevant portion of the 2021 NBPP but did not order any additional relief. ECF No. 41. To ensure that they are not inadvertently running afoul of the Court’s Order, however, Defendants respectfully request clarification from the Court if their understanding of the scope of the Court’s Order is incorrect.

On November 27, 2023, undersigned counsel discussed this motion by email with counsel for Plaintiffs, Paul Hughes, who advised that “Plaintiffs oppose the requested relief on the grounds that they believe it is unlawful. Plaintiffs will file an opposition brief setting forth their position.”

Dated: November 27, 2023

Respectfully submitted,

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