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.

No. 1:22-cv-2604 (JDB)

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Federal Rule of Civil Procedure 56 and Local Rule 7(h)(2), Plaintiffs HIV and Hepatitis Policy Institute, Diabetes Patient Advocacy Coalition, Diabetes Leadership Council, Alyssa Dykstra, Katherine Mertens, and Cynthia Regan respectfully request that the Court issue an order granting summary judgment to them on all claims in their First Amended Complaint and setting aside Defendants' rule, *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. 29,163 (May 14, 2020) (the 2021 NBPP), to the extent it authorizes insurers and other parties not to count manufacturer assistance amounts against patients' cost-sharing responsibilities. Plaintiffs also respectfully request an opportunity to present oral argument on this motion.

As set forth in greater detail in the accompanying memorandum of points and authorities, Plaintiffs are entitled to summary judgment on their claims because: (1) the 2021 NBPP's authorization of copay accumulator programs conflicts with the statutory text of the Affordable Care Act; (2) that authorization conflicts with the text of the existing regulatory definition of cost-sharing,

which the 2021 NBPP does not purport to rescind or interpret; and (3) Defendants' authorization of copay accumulators in the 2021 NBPP is arbitrary and capricious for multiple reasons, including that the agencies' reasoning (a) is based on a misunderstanding of the law, (b) is irrational in several respects, (c) failed to grapple with the agencies' earlier contrary findings or the existence of reliance interests, and (d) treats like cases differently.

For these reasons, summary judgment and vacatur are appropriate.

Dated: February 2, 2023 Respectfully submitted,

/s/ Paul W. Hughes

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