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)

MOTION FOR LEAVE TO FILE A SURREPLY
AND SURREPLY IN OPPOSITION TO THE GOVERNMENT'S
MOTION FOR CLARIFICATION

Plaintiffs respectfully request leave to file a brief surreply, integrated herein, in opposition to the government's motion for clarification (Dkt. 43). Because the government's motion itself contained no legal argument in support of its request, Plaintiffs had no way of knowing the government's legal position until the filing of the government's reply (Dkt. 49). Leave to file this brief surreply is therefore warranted to provide Plaintiffs an opportunity to respond to the government's position, and will not prejudice the government or cause undue delay. Undersigned counsel for Plaintiffs has conferred with counsel for the government, which opposes the requested relief but will not file a separate opposition.

1. On the merits, the government's position is misguided. To be utterly clear: We *are not* asking the Court to require specific, individual enforcement actions against specific, individual insurers that fail to comply with the now-revived 2020 NBPP, either by injunction or otherwise. *See* Pls. Opp. 9 ("[O]ur point is not that the Court can or should require HHS to institute individual enforcement actions against specific insurers."); *id.* at 9-10 (similar). The government's citation of cases like *Northern Air Cargo v. U.S. Postal Service*, 674 F.3d 852 (D.C. Cir. 2012), in which

the district court *did* "issue[] an extraordinary injunction preventing" a particularized agency action (*id.* at 72, 78), is therefore completely beside the point.[1]

2. As to the arguments we actually made, the government has little to say. It does not dispute our demonstration that the Court's vacatur of the 2021 NBPP had the result of reinstating the previously effective version of Section 156.130(h), which permitted copay accumulators *only* where a medically appropriate generic version of a name brand drug is available. *See* Pls. Opp. 3-5; *compare generally* Gov't Reply (not contesting this point). Nor does the government meaningfully contest that HHS cannot lawfully announce a blanket non-enforcement policy. *See generally id.* As we explained (and as the government does not even address), such "deliberate non-enforcement" of a binding regulation "is functionally indistinguishable from suspending" that regulation, and is therefore unlawful unless accomplished through notice-and-comment rulemaking. *Nat'l Ass'n of Mfrs v. SEC.*, 631 F. Supp. 3d 423, 429 (W.D. Tex. 2022); *see, e.g.*, *Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017) (rejecting agency's argument that it "has 'inherent authority' to 'issue a brief stay' of a final rule—that is, not to enforce a lawfully issued final rule—while it reconsiders it"); Pls. Opp. 6-9. And, such action by HHS would essentially nullify this Court's judgment of vacatur, by acting as if the now-vacated regulations continue to govern.

3. Finally, while the government claims that "health plans for 2024 are already being offered to consumers based on a regulatory regime finalized months ago" (Gov't Reply 2), it bears repeating that the government has never asked for a stay, a remand without vacatur, or any other procedurally permissible relief from the legal consequences of the Court's judgment. *See* Pls. Opp. 2-3, 9. Even if the vacatur threatened disruptive consequences—a proposition that is, in any event, belied by both the government's persistent failure to seek relief and the regulated industry's clear

[1] Our reference to injunctive relief (Pls. Op. 9; *see id.* at 2) was only in the event the agency continues to flout the Court's judgment by unlawfully imposing a categorical non-enforcement policy. *See* Op. 24 n.4. Again, we do not contend that the court can or should mandate any particular enforcement actions.

understanding that the pre-2021 regulation now governs (*see* Pls. Opp. 4-5)—the government may not obtain the same results through self-help.

CONCLUSION

The Court should clarify that the agency cannot lawfully suspend the currently effective version of Section 156.130(h) by announcing a blanket policy of non-enforcement.

Dated: December 20, 2023

Respectfully submitted,

/s/ *Paul W. Hughes*

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