UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, *Plaintiffs,* –v– ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services, *et al.*, *Defendants.*	**Civil Action No. 18-2084 (RC)**

NOTICE OF ADMINISTRATIVE DECISIONS

In their Motion for a Preliminary and Permanent Injunction, Plaintiffs stated that, on August 2, 2018, Plaintiff Henry Ford Health System ("Henry Ford") had appealed three administrative claims for reimbursement under the 340B Program to the Office of Medicare Hearings and Appeals ("OMHA"), and had requested review by an Administrative Law Judge ("ALJ"). ECF No. 2-1 at 14 (citing Ex I at 19–22; Ex. J at 20–23; Ex. K at 19–22). On October 30, 2018, the Deputy Chief ALJ issued orders dismissing two of Henry Ford's appeals. *See* Suppl. Ex. I at 23–31; Suppl. Ex. J at 24–32. The Henry Ford employee responsible for managing Henry Ford's administrative appeals under the 340B Program received these decisions on November 27, 2018, and Henry Ford appealed both of the dismissal orders to the Medicare Appeals Council on November 29, 2018. *See* Suppl. Ex. I at 32–36; Suppl. Ex. J at 33–37. The Henry Ford employee has not received the third appeal.

These decisions cast additional doubt on Defendants' argument that Plaintiffs' case should be dismissed for failure to exhaust administrative remedies, *see* ECF No. 15 at 26–27, ECF No. 20 at 10 n.6, and they lend additional support to Plaintiffs' response that further

exhaustion of Plaintiffs' administrative appeals is utterly futile. *See* ECF No. 2-1 at 16–20; ECF No. 16 at 12–14; ECF No. 19 at 1–2. In the dismissal orders, which are identical in their parts, the ALJ concludes that *administrative relief at every appeal level was foreclosed by Department of Health and Human Services ("HHS") regulations*. *See* Suppl. Ex. I at 35 (stating that the challenged reimbursement decision at issue "is not . . . subject to the Medicare claims appeal process," and thus "the appellant did not have the right to a redetermination, a reconsideration, or an ALJ hearing"); Suppl. Ex. J at 36 (same).

Specifically, the ALJ concluded that under the HHS regulations creating certain exceptions to "initial determinations," the reimbursement decisions under the 340B Program that Plaintiffs are challenging are not "initial determinations," and thus cannot be administratively appealed. Suppl. Ex. I at 35 (citing 42 C.F.R. § 405.926(c) and stating that "an issue regarding the computation of the payment amount of program reimbursement of general applicability for which CMS has sole responsibility" is not an "initial determination"); Suppl. Ex. J. at 36 (same). Previously, Defendants had consistently refused to adjudicate Plaintiffs' administrative appeals on the grounds that all administrative and judicial review is precluded by statute. *See, e.g.*, Suppl. Ex. L at 3; Suppl. Ex. N at 3; Suppl. Ex. P at 4. They even refused Plaintiff Henry Ford's request for expedited judicial review, even though expedited judicial review was plainly appropriate here since the only issue to be resolved is the legality of HHS's regulations reducing the reimbursement for 340B drugs, which no administrative body has the authority to resolve. ECF No. 19-1.

Plaintiffs have argued for the past year that they should not be required to exhaust the Medicare administrative appeals process because they challenge a regulation of general applicability that no individual adjudicator within HHS has authority to ignore. *See, e.g.*, ECF

No. 16 at 12–14; *Am. Hosp. Ass'n v. Hargan*, Case 1:17-cv-2447 (RC), Pls.' Reply Br. in Supp. of Mot. for Preliminary Injunction, ECF No. 20 at 16. In response, HHS has repeatedly argued that even this type of challenge must be pursued through the administrative appeals process. *See, e.g.*, ECF No. 15 at 26–27. It is ironic, to put it mildly, that an ALJ has now ruled that an HHS regulation forecloses this precise feature of Plaintiffs' challenge.

Regardless of whether the ALJ is correct in its interpretation of HHS's regulations, it is by now clear beyond cavil that Plaintiffs' administrative appeals are futile. Nevertheless, since this issue is still pending before the Court, Henry Ford dutifully has appealed the two ALJ dismissal decisions to the next level, the Medicare Appeals Council. *See* Suppl. Ex. I at 32–36; Suppl. Ex. J at 33–37. But there can be no doubt that those appeals will be dismissed or denied—whether based on the ALJ's reasoning, because of HHS's position that administrative and judicial review is precluded by statute, or because the Medicare Appeals Council, like every other adjudicator within HHS, has no authority to depart from HHS regulations and rule in Plaintiffs' favor on the merits of their challenge. *See* 42 C.F.R. § 405.1063(a).

Plaintiffs urge the Court to rule that further exhaustion would be entirely futile (*see Tataranowicz v. Sullivan*, 959 F.2d 268, 274–75 (D.C. Cir. 1992); *Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103, 110–12 (D.D.C. 2015), and to grant Plaintiffs' motion for a preliminary and permanent injunction.

Dated: December 3, 2018

Respectfully submitted,

/s/ William B. Schultz

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CERTIFICATE OF SERVICE

I hereby certify that, on December 3, 2018, I caused the foregoing to be electronically served on counsel of record via the Court's CM/ECF system.

/s/ Ezra B. Marcus
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