

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)

MOTION FOR A PERMANENT INJUNCTION COVERING THE 2019 OPPTS RULE¹

In November 2018, Defendants issued a regulation requiring that, for calendar year 2019, the Centers for Medicare & Medicaid Services (CMS) reimburse drugs purchased under section 340B of the Public Health Services Act (“340B drugs”) by using a methodology based on Average Sales Price minus 22.5%, just as they had done for calendar year 2018. CMS, Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 83 Fed. Reg. 58,818, 58,979–81 (Nov. 21, 2018) (“2019 OPPTS Rule”). Defendants explained that they were “continuing the 340B Program policies that were implemented in [calendar year] 2018”—*i.e.*, the policy of “pay[ing] for separately payable Medicare Part B drugs . . . that are acquired through the 340B Program at ASP minus 22.5 percent.” *Id.* at 58,980–81.

¹ The parties have conferred and Defendants have indicated that they do not consent to this Motion.

On December 27, 2018, this Court held unlawful the reduced rate for 340B Drugs in the 2018 OPSS Rule on the grounds that it exceeded the Secretary's authority under 42 U.S.C. § 1395l(t)(14)(iii)(II). ECF Nos. 24, 25. The Court declined to apply its injunction to the 2019 OPSS Rule because, at that time, Plaintiffs had not yet "presented the Secretary with a concrete claim for reimbursement under the 2019 rule." ECF No. 25 at 34 n.25.

On January 10 and 11, 2019, Plaintiff Henry Ford Health System (HFHS) presented the Secretary with two claims for separately payable, outpatient 340B drugs purchased in 2019, and on January 30 and February 1, 2019, HFHS received reduced reimbursements on those claims pursuant to the same payment methodology that this Court held unlawful with respect to the 2018 OPSS Rule. *See* Exs. A–B (claim documents). The Court has granted Plaintiffs' unopposed motion to file a supplemental complaint adding a claim challenging the provisions of the 2019 OPSS Rule that carry forward the unlawful reimbursement rate for 340B drugs from the 2018 OPSS Rule. Min. Order of Feb. 8, 2019.

Now that Plaintiffs' challenge to the 2019 OPSS Rule is part of this case, the Court should hold the 2019 OPSS Rule unlawful and issue a permanent injunction as to the 2019 OPSS rule, just as it did for the 2018 OPSS Rule. On the merits, Plaintiffs' challenges to the 2018 and 2019 OPSS Rules are identical. In issuing the 2019 OPSS Rule, Defendants explained that it "continue[s] the 340B Program policies that were implemented in [calendar year] 2018." 83 Fed. Reg. at 58,981. For all of the reasons that the Court has already articulated with respect to the 2018 OPSS Rule, *see* ECF No. 25 at 23–30, the 2019 OPSS Rule is *ultra vires* and unlawful.

In addition, the Court's reasons for rejecting Defendants' non-merits defenses with respect to the 2018 OPSS Rule, *see* ECF No. 25 at 14–23, apply equally to the 2019 OPSS Rule. If review of the 2018 OPSS Rule is not statutorily precluded under 42 U.S.C. § 1395l(t)(12),

either because the preclusion provisions cited by Defendants do not apply or because Defendants' action is *ultra vires*, see ECF No. 25 at 19–23, then neither is review of the 2019 OPPS Rule precluded. And if further administrative exhaustion of the decisions that Plaintiffs received under the 2018 OPPS Rule can be waived as futile, see ECF No. 25 at 14–19, then the same is true of the decisions that HFHS has received under the 2019 OPPS Rule. Although HFHS has not currently pursued its 2019 claims as far through the administrative appeals process as Plaintiffs had pursued their 2018 claims at the time the Court issued its ruling, HFHS has received reimbursement decisions from its Medicare Administrative Contractor that adhere to the reduced reimbursement rate in the 2019 OPPS Rule. Ex. A at 2; Ex. B at 2. Just as with Plaintiffs' appeals under the 2018 OPPS Rule, “no administrative review body would even have authority to alter or deviate from” that rate. ECF No. 25 at 18 (citing 42 C.F.R. § 405.1063(a)). There is likewise “no reason to believe that the agency might overturn the regulation, should Plaintiffs be given additional opportunities to raise their arguments through the administrative process.” *Id.* at 17. The decisions that HFHS has received are thus “final decisions” for purposes of 42 U.S.C. § 405(g), and further exhaustion of administrative remedies should be waived as futile.

Given that it is still early in 2019, if the Court grants this Motion, it will be in a position to remedy the unlawful 2019 OPPS Rule *prospectively*, at least in part. See Suppl. Compl., ECF No. 34-3, Prayer for Relief ¶ B. To that effect, Plaintiffs ask that the Court order Defendants to issue an interim final rule within 30 days of the Court's order, effective no more than 30 days later, providing that 340B drugs will be reimbursed using the methodology based on the statutory default rate of ASP plus 6%—that is, the same rate that Defendants applied in 2017 and the same rate they are currently applying in 2019 for all separately payable drugs *not* purchased under the

340B Program (and for some 340B Drugs that were exempted from the rate reduction). Plaintiffs recognize that a 30-day timeframe for issuing an interim final rule is short, but it is in the interest of all parties that Defendants correct the unlawful aspects of the 2019 OPPS Rule as quickly as possible. Given Defendants' stated concerns regarding retrospective remedies, *see* Gov't Brief on Remedy, ECF No. 31 at 7–9, Defendants should want a quick forward-looking fix for the remainder of 2019 just as much as Plaintiffs do.

For all 340B drugs where claims were paid before the effective date of the interim final rule, Plaintiffs ask that the Court implement the same retrospective remedy that plaintiffs have proposed for 2018. See Plaintiffs Supplemental Brief on Remedies, ECF No. 32 at 2, 10.

CONCLUSION

Plaintiffs respectfully request that the Court grant their Motion for a Permanent Injunction Covering the 2019 OPPS Rule. Plaintiffs further request that the Court (1) order HHS to issue an interim final rule within 30 days, and effective 30 days after issuance, that corrects the statutory violation by providing for reimbursement of 340B drugs during the remaining portion of calendar year 2019 at a rate of ASP plus 6%; and (2) for 2019 340B drug claims that were paid prior to the effective date of the interim final rule, order HHS to recalculate the payments due to Hospital Plaintiffs and hospital members of Association Plaintiffs to ensure that those hospitals receive payment based on the statutory default rate of ASP plus 6% as provided in the 2017 OPPS rule. The order should require that hospitals receive a payment that equals the

difference between the amount they received and the amount to which they were entitled to using the ASP plus 6% methodology, plus interest.

Dated: February 11, 2019

Respectfully submitted,

/s/ William B. Schultz

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CERTIFICATE OF SERVICE

I hereby certify that, on February 11, 2019, I caused the foregoing to be electronically served on counsel of record via the Court's CM/ECF system.

/s/ William B. Schultz
William B. Schultz

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[PROPOSED] ORDER

Upon consideration of Plaintiffs' Motion for a Permanent Injunction Covering the 2019 OPPS Rule, it is hereby

ORDERED that the Motion is **GRANTED**. It is

FURTHER ORDERED that, within 30 days of this Order, Defendants shall issue an interim final rule, effective no more than 30 days later, providing that for the remainder of calendar year 2019, separately payable drugs purchased under Section 340B of the Public Health Services Act will be reimbursed at the same rate as other separately payable drugs (based on Average Sales Price plus 6%). It is

FURTHER ORDERED that, for 2019 340B drug claims that were paid prior to the effective date of the interim final rule, Defendants shall recalculate the payments due to Hospital Plaintiffs and hospital members of Association Plaintiffs to ensure that those hospitals receive payment based on the Average Sales Price plus 6% methodology, as provided in the 2017 OPPS rule. Defendants shall ensure that these hospitals receive a payment that equals the difference

between the amount they received and the amount to which they were entitled using the Average Sales Price plus 6% methodology, plus interest.

Dated: _____

RUDOLPH CONTRERAS
United States District Judge