

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)

**OPPOSITION TO GOVERNMENT’S MOTION TO DISMISS AND REPLY IN
SUPPORT OF MOTION FOR A PERMANENT INJUNCTION COVERING THE 2019
OPPS RULE**

In a highly unusual filing, Defendants seek to defend the 2019 OPPS Rule with arguments that Defendants forthrightly acknowledge the Court has already rejected. *See* Gov’t Mem. in Supp. of Mot to Dismiss New Claim & Opp’n to Mot. for Perm. Inj. With Respect to 2019 OPPS Rule (“Gov’t Mot.”), ECF No. 42 at 2 (“Defendants recognize that the Court has rejected those arguments in the context of the 2018 OPPS Rule . . .”). Although Defendants ask the Court to “reconsider its conclusion in the context of the 2019 OPPS Rule,” *id.*, Defendants recite exactly the exact same arguments that they raised in defense of the 2018 OPPS Rule and give no reason whatsoever that the result should be different for the 2019 OPPS Rule. Plaintiffs respectfully ask the Court to issue a permanent injunction holding the 2019 OPPS Rule unlawful under 42 U.S.C. § 1395l(t)(14)(A)(iii), just as the Court did with respect to the 2018 OPPS Rule.

As for the remedy, Defendants simply incorporate all of the same remedy arguments they have raised with respect to the 2018 OPPS Rule, and, in doing so, they fail to recognize that the 2019 OPPS Rule can be remedied *prospectively*, in part, given that it is still early in the year.

The need to implement a remedy at a time when it can be done prospectively is especially acute given Defendants' intransigence regarding retrospective changes to the OPPS system. *See* Gov't Remedy Brief, ECF No. 31 at 7–9. The sooner a prospective remedy is implemented, the shorter the portion of 2019 that will be subject to the parties' disputes regarding retrospective remedies. Given Defendants' refusal to engage on the issue of an appropriate prospective remedy, the Court should implement Plaintiffs' proposal and order Defendants to issue an interim final rule within 30 days, effective no more than 30 days later, providing that 340B drugs will be reimbursed at 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). As for a retrospective remedy for all 340B drugs where claims were paid in 2019 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* Pls.' Suppl. Br. on Remedies, ECF No. 32 at 2, 10.

The Court should not simply remand the case and take Defendants up on their offer to “craft an appropriate remedy” on their own. Gov't Mot. at 4. Defendants' continued efforts to re-litigate the merits amount to a dispute that any remedy is warranted at all, and there is no reason to believe that they will craft an “appropriate” remedy on their own.

The Court should also deny Defendants' alternative request for a stay. *See* Gov't Mot. at 4. The 2019 OPPS Rule is only effective for one year, and time is of the essence if there is any chance of the unlawful rate change being remedied prospectively. Plaintiffs have offered Defendants every possible opportunity to work with Plaintiffs to move this litigation along more quickly so as to reach a final resolution of Plaintiffs' challenge that can be implemented once and

for all. Instead, Defendants have resisted Plaintiffs' efforts to identify a remedy that accounts for the interests of all parties at every step of the way. *See* Gov't Mot.; Gov't Remedy Brief. Defendants' stay request is nothing more than another attempt to avoid bringing reimbursements for 340B Drugs into compliance with the law.

CONCLUSION

Plaintiffs respectfully request that the Court grant their Motion for a Permanent Injunction Covering the 2019 OPPTS 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 OPPTS rule. The order should require that hospitals receive a payment that equals the difference between the amount to which they were entitled to using the ASP plus 6% methodology and the amount they received, plus interest.

Dated: February 26, 2019

Respectfully submitted,

/s/ William B. Schultz

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CERTIFICATE OF SERVICE

I hereby certify that, on February 26, 2019, I caused the foregoing to be electronically served on counsel of record via the Court's CM/ECF system.

/s/ Ezra B. Marcus

Ezra B. Marcus