

**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)

**PLAINTIFFS’ MOTION FOR A FIRM DATE BY WHICH DEFENDANTS MUST
PROPOSE A REMEDY FOR VIOLATIONS OF THE MEDICARE ACT¹**

Defendants issued regulations requiring that, for calendar years 2018 and 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%.² On December 27, 2018, this Court held unlawful the reduced rate for 340B drugs in the 2018 OPSS Rule on the ground that it exceeded the Secretary’s authority under 42 U.S.C. § 1395l(t)(14)(iii)(II) (ECF Nos. 24, 25), and on May 6, 2019, it held unlawful the reduced rate for 340B drugs in the 2019 OPSS Rule on the same ground (ECF Nos. 49, 50). With regard to the appropriate remedy, the Court remanded the matter to HHS to give it “the first

¹ Defendants oppose this motion.

² Medicare Program, Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 52,356 (Nov. 13, 2017) (2018 OPSS Rule); Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 83 Fed. Reg. 58,818 (Nov. 21, 2018) (2019 OPSS Rule).

crack at crafting appropriate remedial measures.” ECF No. 50 at 2. The Court also directed the parties to submit a status report on August 5, 2019, regarding the agency’s progress on remand to remedy the issues raised in this litigation concerning the 2018 and 2019 OPPS rules. ECF No. 50 at 22.

Plaintiffs request a modification in the Court’s order, namely that it establish a firm date, June 28, 2019, by which HHS must propose a remedy to the Court. A date of June 28, 2019, would allow Defendants more than seven weeks from the court’s decision to identify a remedy. Plaintiffs believe that it is important that the Court require HHS to propose its remedy by the end of June 2019 or shortly thereafter, since unless there is a Court order on the remedy in this case this summer, Defendants may issue a 2020 OPPS rule reducing reimbursements for 340B drugs by nearly 30% in violation of law, just as they did in 2018 and 2019. While the final OPPS rule is typically issued in November of the prior year, CMS typically issues its proposed rule in late July, although the proposal could be delayed for a short period of time (or CMS could issue a reproposal) to take into account a ruling on remedy in this case.³

The absence of a firm and expeditious deadline for submitting a remedy to the Court also would severely disadvantage 340B hospitals and could harm the Medicare program. 340B hospitals as a group have been losing \$25 million per week since January 1, 2018, because HHS continues to apply the illegal rate of ASP minus 22.5%. And, as noted above, unless HHS proposes a remedy expeditiously, with which the Plaintiffs agree or if the parties disagree that the Court can rule on, it seems likely that HHS will use the same illegal formula in its 2020 OPPS rule. With each passing day and month, more claims are being underpaid and thus more

³ Plaintiffs recognize that a final decision of this court could be stayed pending appeal, but nevertheless maintain that it will be more difficult for CMS to issue a third illegal rule for 2020 once this court has issued a final decision for 2018 and 2019.

claims may be the subject of retrospective relief, which this Court has found could be difficult to implement. ECF No. 31 at 7-9; ECF No. 50 at 18-19. In addition, because Plaintiffs have no assurance that, in the end, they are going to be made whole by the remedy approved by the Court, and Plaintiffs' underpayments continue to grow, time is of the essence.

Delaying the remedy could also harm the Medicare Trust Fund. The Court has indicated that either it or the agency may determine that a remedy need not be budget neutral. In that case, the greater the number of underpayments that must be remedied, the larger the cost will be for the Trust Fund. Thus, expeditiously deciding on the remedy will conserve resources held by the Trust Fund. This Court should ensure that Defendants are not permitted to continue to perpetuate the illegal payments that have continued for nearly two years, and exacerbate the potential disruption of the ultimate resolution.

A deadline of June 28, 2019 for a proposed remedy is reasonable in light of the fact that Defendants have known since this Court's December 27, 2018 opinion that a remedy would be required. Moreover, the briefing that the Court ordered on remedies identified only two options for Defendants to consider. First is the option proposed by Plaintiffs pursuant to which HHS, for past claims, would pay Plaintiffs the difference between the amount they received and the amount to which they were entitled and for future claims would pay Plaintiffs the amount to which they are entitled. ECF No. 32 at 2-4. The other option is for Defendants to increase the reimbursement for 340B drugs prescribed in one or more future years to make up the difference between what Plaintiffs were paid and what they should have been paid. This is the approach that was adopted in *Shands Jacksonville Med. Ctr. v. Azar*, 366 F.Supp.3d 32, 46-47 (D.D.C. 2018). It is reasonable to expect that, by June 28, 2019, Defendants can identify an option and

either obtain agreement from Plaintiffs or present it to this Court so that the Court can identify the appropriate remedy.

Accordingly, Plaintiffs respectfully request that the Court require the Defendants to submit a status report no later than June 28, which identifies their proposed remedy. A Proposed Order is attached.⁴

Dated: May 10, 2019

Respectfully submitted,

/s/ William B. Schultz

William B. Schultz (DC Bar No. 218990)

Margaret M. Dotzel (DC Bar No. 425431)

Ezra B. Marcus (DC Bar No. 252685)

ZUCKERMAN SPAEDER LLP

1800 M Street, NW, Suite 1000

Washington, DC 20036

Tel: 202-778-1800

Fax: 202-822-8136

[wschultz@zuckerman.com](mailto:w Schultz@zuckerman.com)

mdotzel@zuckerman.com

emarcus@zuckerman.com

Attorneys for Plaintiffs

⁴ Local Rule 7 provides that Defendants have 14 days or “such other time as the Court may direct” to file an opposition to this motion. Because time is of the essence and because any response should be straightforward and brief, Plaintiffs respectfully request that the Court order Defendants to respond to this Motion within 7 days.

CERTIFICATE OF SERVICE

I hereby certify that, on May 10, 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