

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 LEAVE TO FILE SUPPLEMENTAL COMPLAINT¹

In November 2018, Defendants issued a regulation stating that, for calendar year 2019, they would reimburse drugs purchased under section 340B of the Public Health Services Act (“340B drugs”) using a methodology that relies on Average Sales Price (ASP) 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 OPSS Rule”). Defendants’ rationale for this reimbursement rate was that it “continue[d] 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.

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.

¹ The parties have conferred and Defendants have indicated that they do not oppose this motion.

§ 1395l(t)(14)(iii)(II). ECF Nos. 24, 25. The Court declined to enjoin the 2019 OPPS Rule because, at that time, Plaintiffs had not yet “presented the Secretary with a concrete claim for reimbursement under the 2019 rule,” and “[t]his Court [wa]s thus foreclosed from reviewing the 2019 rule.” Mem. Op. at 34 n.25.

Henry Ford Health System, one of the plaintiffs in this action, has now presented the Secretary with claims under the 2019 OPPS Rule and has received reduced reimbursements pursuant to the same payment methodology that this Court held unlawful with respect to the 2018 OPPS Rule. *See* Exs. A–B (claim documents). Plaintiffs seek to file a supplemental complaint to add allegations regarding these developments and to add a claim challenging the provisions of the 2019 OPPS Rule that carry forward the unlawful reimbursement rate for 340B drugs from the 2018 OPPS Rule. *See* Ex. C (proposed supplemental complaint); Ex. D (redline with original complaint).²

Permitting Plaintiffs to add a challenge to the 2019 OPPS Rule to this case via a supplemental pleading is warranted under Federal Rule of Civil Procedure 15(d). Motions to file supplemental pleadings “are to be freely granted when doing so will promote the economic and speedy disposition of the entire controversy between the parties, will not cause undue delay or trial inconvenience, and will not prejudice the rights of any other parties to the action.” *Powell v. IRS*, 263 F. Supp. 3d 5, 7 (D.D.C. 2017) (quoting *Hall v. CIA*, 437 F.3d 94, 101 (D.C. Cir. 2006)).

There could hardly be a clearer example of a supplemental pleading “promot[ing] the economic and speedy disposition of the entire controversy between the parties.” *Id.* Since the

² This is technically a “supplemental pleading,” not an “amended” pleading, because it “sets forth ‘transactions or occurrences or events which have happened since the date of the pleading sought to be supplemented.’” *United States v. Hicks*, 283 F.3d 380, 385 (D.C. Cir. 2002) (quoting Fed. R. Civ. P. 15(d)). As the D.C. Circuit has explained, “the distinction is in most instances of little moment.” *Id.*

beginning of this case, it has been apparent that the Court’s ruling with respect to the 2018 OPPS Rule could implicate the legality of the 2019 OPPS Rule. *See* Compl., ECF No. 1 ¶ 39 (observing that “the Proposed 2019 OPPS Rule would continue the 340B Program policies that were implemented in calendar year 2018” (citation and alteration omitted)); *id.* Prayer for Relief ¶ (E) (seeking an order “[d]irecting Defendants to conform the payment methodology that they use for 340B drugs in 2019 . . . to the requirements of the Social Security Act”). In its memorandum opinion, the Court concluded that it could not formally order any relief with respect to the 2019 OPPS Rule at a time when Plaintiffs had not presented claims for payment under that Rule. Mem. Op. at 34 n.25. Now that Plaintiffs have presented claims under the 2019 OPPS Rule, bringing that Rule into the case would avoid a situation in which the 2019 Rule remains technically unaffected by this lawsuit despite being obviously unlawful under the reasoning of the Court’s Memorandum Opinion [and Order]. Bringing the 2019 OPPS Rule into the case would also allow for a coherent and final resolution to Plaintiffs’ challenge.

CONCLUSION

Plaintiffs respectfully ask the Court for permission to file the attached supplemental complaint, which adds a challenge to the 2019 OPPS Rule.

Dated: February 7, 2019

Respectfully submitted,

/s/ William B. Schultz

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CERTIFICATE OF SERVICE

I hereby certify that, on February 7, 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