

**IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

AMERICAN HOSPITAL ASS'N, *et al.*,

Plaintiffs-Appellees,

v.

ALEX M. AZAR II, *et al.*,

Defendants-Appellants.

No. 19-5048

**UNOPPOSED MOTION TO HOLD APPEAL IN ABEYANCE
PENDING DISTRICT COURT'S ENTRY OF FINAL JUDGMENT**

The government defendants respectfully request that the Court hold the appeal recently filed in this matter in abeyance pending the entry of final judgment. Plaintiffs have authorized us to state that they consent to this motion.

1. This case concerns a challenge brought by plaintiffs to a rulemaking that adjusted for calendar year 2018 the payments made by the Centers for Medicare & Medicaid Services (CMS) under the Outpatient Prospective Payment System (OPPS) in Medicare Part B for certain drugs covered by a program known as the 340B Program.¹ Plaintiffs contend that the U.S. Department of

¹ This case presents a materially identical challenge to claims presented to this Court in 2018. *See American Hosp. Ass'n v. Azar*, 895 F.3d 822 (D.C. Cir. 2018). This Court dismissed that action because plaintiffs failed to present any concrete claim for reimbursement to the Secretary for a final decision, and thus the district court lacked subject-matter jurisdiction to hear the claims. *Id.* The parties now

Health and Human Services exceeded its statutory authority when it set the reimbursement rate lower than it had in previous years. Defendants, HHS and the Secretary, argued that the rate adjustment was statutorily authorized and was justified by developments in the market.

2. The OPPS System provides payment to hospitals at prospectively determined rates for services in the upcoming year. The Secretary has broad discretion to develop a classification system for covered outpatient services and to make adjustments to the OPPS. *See* 42 U.S.C. § 1395l(t). Congress also shielded the Secretary’s development of and adjustments to the OPPS payment system from administrative and judicial review. *Id.* § 1395l(t)(12). This Court has recognized that, because the OPPS payment schedule is budget-neutral—“piecemeal review of individual payment determinations could frustrate the efficient operation of the complex prospective payment system.” *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004).

3. Plaintiffs sought a permanent injunction, asking the district court to vacate the Secretary’s rate reduction, require the Secretary to apply previous reimbursement rates for the pending claims from 2018, and require the Secretary to pay plaintiffs the difference between the reimbursements under the new rates and the reimbursements they would have received under previous rates.

agree that plaintiffs have presented reimbursement claims covered by the 2018 OPPS Rule.

4. Defendants sought to dismiss the complaint, arguing that Congress expressly precluded judicial review of rate adjustments in the OPPS scheme, that the Secretary's action was wholly discretionary and thus, could not be reviewed, and that plaintiffs had failed to exhaust their administrative remedies. The government defendants also argued that the Secretary had statutory authority to set the reimbursement rate at the 2018 level of average sales price minus 22.5%.

5. On December 27, 2018, the district court issued an order denying the government's motion to dismiss and granting plaintiffs request for a permanent injunction. *See* Dkt. No. 25, 1:18-cv-2084 (Dec. 27, 2018). The court declined to decide whether the statutory review bar applied, concluding instead that it had jurisdiction to review the claims because the Secretary's action was *ultra vires* and thus not subject to the statutory judicial review bar. The court relied on the "rate reduction's magnitude and its wide applicability" to conclude that the Secretary exceeded his authority to "adjust" rates under 42 U.S.C. § 1395l(t)(14)(A)(iii).

6. Recognizing that "vacatur and other relief sought by Plaintiffs [we]re likely to be highly disruptive" in light of the "budget neutrality requirement," Op. 34, the district court did not order any specific relief, but instead sought "supplemental briefing from the parties addressing the relief's proper scope and implementation." Op. 36. Briefing on the remedial question concluded on February 26, 2019, but the district court has not yet issued any decision.

7. On February 22, 2019, the government defendants filed a notice of appeal from the district court's December 27, 2018 decision granting plaintiffs' request for a permanent injunction. *See* 28 U.S.C. § 2107 (setting the time to file a notice of appeal as 60 days when the United States is a party).

8. Under 28 U.S.C. § 1292(a), this Court has jurisdiction to review the order granting the injunction. The government respectfully requests, however, that this Court hold the appeal in abeyance until the district court resolves the question on the scope and implementation of relief so that this Court can resolve any appeal regarding the scope of the injunction along with the underlying lawfulness of the Secretary's action. Although the filing of a notice of appeal normally divests the district of jurisdiction, the court retains jurisdiction to effectuate the injunction even after a notice of appeal has been filed. Granting the motion will conserve the resources of the Court and the parties and avoid duplicative briefing.

CONCLUSION

For the foregoing reasons, the Court should grant the request to hold the appeal in abeyance pending the district court's resolution of the scope of the injunction and entry of final judgment.

Respectfully submitted,

MARK B. STERN

/s/ Laura E. Myron

LAURA E. MYRON

(202) 514-4819

Attorneys, Appellate Staff

Civil Division

U.S. Department of Justice

950 Pennsylvania Ave., NW

Room 7228

Washington, D.C. 20530

MARCH 2019

CERTIFICATE OF COMPLIANCE

I hereby certify that this response complies with volume limitations of Fed. R. App. P. 27(d)(2)(A) because it contains 756 words, excluding the parts of the response exempted under Rule 32(f), according to the count of Microsoft Word. I further certify that this response also complies with the typeface and type-style requirements of Fed. R. App. P. 27(d)(1)(E), 32(a)(5), and 32(a)(6) because this document has been prepared in Microsoft Word in 14-point Garamond, which is a proportionally spaced font.

s/ Laura E. Myron

LAURA E. MYRON

CERTIFICATE OF SERVICE

I hereby certify that on March 5, 2019, I electronically filed the foregoing response with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ Laura E. Myron

LAURA E. MYRON