

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

OCHSNER CLINIC FOUNDATION D/B/A)
OCHSNER MEDICAL CENTER,)
1514 Jefferson Hwy, New Orleans, LA 70121)

OCHSNER MEDICAL CENTER - KENNER,)
L.L.C., 180 W Esplanade Ave., Kenner, LA)
70065-2467)

EAST BATON ROUGE MEDICAL CENTER)
LLC D/B/A OCHSNER MEDICAL CENTER)
BATON ROUGE, 17000 Medical Center)
Drive, Baton Rouge, LA 70816)

OCHSNER MEDICAL CENTER -)
HANCOCK LLC, 149 Drinkwater Rd)
Bay Saint Louis, MS 39520)

SOUTHERN REGIONAL MEDICAL)
CORPORATION D/B/A LEONARD J.)
CHABERT MEDICAL CENTER, 8166 Main)
St, Houma, LA 70360)

HOSPITAL SERVICE DISTRICT OF THE)
PARISH OF ST BERNARD D/B/A ST.)
BERNARD PARISH HOSPITAL, 8000 W)
Judge Perez Dr., Chalmette, LA 70043)

HOSPITAL SERVICE DISTRICT NO 1 OF)
ST. CHARLES PARISH D/B/A ST.)
CHARLES PARISH HOSPITAL, 1057 Paul)
Maillard Rd, Luling, LA 70070)

Plaintiffs,)

v.)

XAVIER BECERRA, in his official capacity)
as Secretary, United States Department of)
Health and Human Services,)
200 Independence Ave. S.W.)
Washington, District of Columbia 20201,)

Defendant.)

Civil Action No. _____

COMPLAINT

Plaintiffs, Ochsner Clinic Foundation d/b/a Ochsner Medical Center; Ochsner Medical Center - Kenner, L.L.C.; East Baton Rouge Medical Center LLC d/b/a Ochsner Medical Center Baton Rouge; Ochsner Medical Center - Hancock LLC; Southern Regional Medical Corporation d/b/a Leonard J. Chabert Medical Center; Hospital Service District of the Parish of St Bernard d/b/a St. Bernard Parish Hospital; and Hospital Service District No 1 of St. Charles Parish d/b/a St. Charles Parish Hospital (collectively “Plaintiffs”) are hospitals that participate in the Medicare program and purchase drugs through the 340B Drug Pricing Program, bring this complaint against Defendant Xavier Becerra, in his official capacity as Secretary of Health and Health Human Services (“Secretary”), and allege as follows:

INTRODUCTION

1. Plaintiffs seek judicial review of a final determination of the Secretary regarding the Hospital Outpatient Prospective Payment System (“OPPS”) and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs for Calendar Years (“CYs”) 2018, 2019, 2020, 2021, and 2022. *See* 82 Fed. Reg. 52356, 52493-511, 52622-25 (Nov. 13, 2017) (“CY 2018 Final Rule”); 83 Fed. Reg. 58818, 58079-81 (Nov. 21, 2018) (“CY 2019 Final Rule”) 84 Fed. Reg. 61142, 61317-27 (Nov. 12, 2019) (“CY 2020 Final Rule”), 85 Fed. Reg. 85866, 86042-55 (Dec. 29, 2020) (“CY 2021 Final Rule”), 86 Fed. Reg. 63458, 63644-49 (Nov. 16, 2021) (“CY 2022 Final Rule”) (collectively, the “Final Rules”). Specifically, Plaintiffs challenge the Secretary’s determination in the Final Rules to reduce Medicare reimbursement for prescription drugs purchased by certain safety net hospitals at prices required by section 340B of the Public Health Service Act (“PHSA”) (the “340B Program”).

2. Plaintiffs bring this action under the Social Security Act, 42 U.S.C. § 1395, *et seq.* (the “Medicare statute”) and the Administrative Procedure Act, 5 U.S.C. §§ 551, *et seq.* (the “APA”). The Plaintiffs allege that the Secretary acted *ultra vires* and exceeded his scope of authority under the Medicare statute in contravention of Congressional intent by reducing reimbursement payment for drugs purchased under the 340B Program.

3. Congress enacted the 340B Program in 1992, lowering the cost of drugs for certain public and not-for-profit hospitals (like Plaintiffs) and federally funded clinics serving large numbers of low-income patients. By so doing, Congress enabled these hospitals to “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” H.R. Rep. No. 102-384(II), at 12 (1992); *see also* 82 Fed. Reg. at 52493 & n. 18 (quoting House Report and noting that “[t]h statutory intent of the 340B Program is to maximize scarce Federal resources as much as possible, reaching more eligible patients”).

4. As this Court explained, “hospitals participating in the 340B Program purchase 340B drugs at steeply discounted rates, and when those hospitals prescribe the 340B drugs to Medicare beneficiaries, they are reimbursed by HHS at OPPS rates.” *Am. Hosp. Ass’n v. Azar*, 348 F. Supp. 3d 62, 69 (D.D.C. 2018), *reversed by Am. Hosp. Ass’n v. Azar*, 967 F.3d 818, D.C.Cir., 2020), *cert. granted by Am. Hosp. Ass’n v. Azar*, 141 S. Ct. 2883 (July 2, 2021), *reversed and remanded by Am. Hosp. Ass’n v. Becerra*, 142 S.Ct. 1896 (June 15, 2022).

5. The Final Rules eliminate all, or nearly all, of the differential between Medicare OPPS reimbursement rates and the discounted purchase costs mandated for 340B hospitals. The Secretary’s decision to reduce payment rates in all five years is a violation of both the Secretary’s authority under the Medicare statute and the purpose and design of the PHSA provisions establishing the 340B Program. It is also arbitrary and capricious agency action under the APA.

6. Starting January 1, 2018 (the effective date of the CY 2018 Final Rule), the Secretary began reimbursing covered outpatient drugs and biologicals acquired through the 340B Program at each drug's average sales price ("ASP") minus 22.5 percent. The Secretary extended that payment reduction through CYs 2019 through 2022. The CY 2020 Final Rule also extended the payment reduction to non-excepted off-campus provider-based departments, which policy remains in effect to the present.

7. From April, 2019 through February, 2020, Plaintiffs presented claims to the Secretary's claims processing contractors (the Medicare administrative contractors, or "MACs") challenging the payment reduction pursuant to the claims dispute process set forth in 42 U.S.C. § 1395ff. An example of a dispute letter, but without the accompanying data run, is included as **Exhibit A**. The MACs did not respond to these dispute letters.

8. The MACs presumably did not respond to these dispute letters because of their policies that they would not honor the statutory claims appeal processes for claims for reimbursement for 340B drugs. One of the MACs serving the Plaintiffs states that it "cannot accept appeals involving the application of the 340B payment adjustment." Accordingly the MAC categorically pronounces that it "will dismiss these redetermination requests." The other MAC similarly states that it is acting "[i]n accordance with Medicare's national payment policy." Under this policy "administrative review is not available for applicable drugs acquired under the 340B drug program that are reimbursed under Outpatient Prospective Payment System (OPPS)." As a result, without exception, the MAC asserts that "[a]ppel requests for reimbursement of drugs purchased through the 340B program will be dismissed." Screen shots from the MACs' websites are included as **Exhibit B**. Given the futility of submission of these disputes, as evidenced by the

lack of a response to its dispute letters as well as the statements on the MACs' websites, the Plaintiffs suspended their submission practices.

9. This Court has found that, as to CYs 2018 and 2019, the Secretary exceeded his authority when he reduced the 2018 and 2019 Medicare reimbursement rate for drugs covered by the 340B Program. *See Am. Hosp. Ass'n*, 348 F. Supp. 3d at 79-83. On appeal, however, the Circuit Court for the District of Columbia found that the Secretary's interpretation is not "directly foreclosed" by the statute, and on that basis upheld the Secretary's action. *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 828 (DC Cir. July 31, 2020), *cert. granted by Am. Hosp. Ass'n v. Azar*, 141 S. Ct. 2883 (July 2, 2021), *reversed and remanded by Am. Hosp. Ass'n v. Becerra*, 142 S.Ct. 1896 (June 15, 2022). The Supreme Court granted certiorari and issued a decision on June 15, 2022. Like the District Court, the Supreme Court gave a close reading to the statute and declared that the reimbursement cuts were "contrary to the statute and unlawful." *Am. Hosp. Ass'n v. Becerra*, No. 20-1114, slip op. at *8 (U.S. June 15, 2022).¹ The Supreme Court has thus reversed the DC Circuit Court opinion and remanded to the lower courts for further action. *Id.*

10. The Supreme Court decision conclusively confirms that the Secretary acted, and continues to act, unlawfully by paying less than ASP plus 6 percent for 340B drugs. The Plaintiffs' dispute letters have thus rightfully demanded that the MACs pay the plaintiffs the full amount owed under the statute. Consistent with the Supreme Court's decisions and their rights under Medicare claims appeals statute (42 U.S.C. § 1395ff), Plaintiffs bring this action seeking declaratory relief from the Secretary's 340B Program payment reductions for CYs 2018 through 2022. (The 2020, 2021, and 2022 payment reductions are the same as the 2018 and 2019

¹ The Westlaw version cites to *Am. Hosp. Ass'n v. Becerra*, 142 S. Ct.1896 (2022). Since this is a new case, the version does not have formatted page numbers. The citations listed in the Complaint are to the Slip Opinion.

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