

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

RUTH E. KANTOR, M.D.,

v.

XAVIER BECERRA,¹ in his
official capacity as Secretary
of the Department of
Health and Human Services

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: Civil Action No. DKC 20-2475

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MEMORANDUM OPINION

Presently pending and ready for resolution in this action for judicial review of an adverse agency decision is Defendant's Motion to Dismiss (ECF No. 12). The issues have been fully briefed, and the court now rules, no hearing being deemed necessary. Local Rule 105.6. For the following reasons, the motion to dismiss will be denied and the parties will be directed to show cause why the case should not be remanded.

I. Background

The following facts are derived from the administrative record preceding this appeal and the pleadings.

A. The Statutory and Regulatory Framework

Medicare is a federally funded health insurance program for the elderly and disabled. It is governed by Title XVIII of the

¹ The complaint named Alex M. Azar, former Secretary of Health and Human Services ("HHS") as Defendant. (ECF No. 1). As of the time of the filing of this opinion, Xavier Becerra now serves as HHS Secretary ("Secretary"). Pursuant to Fed.R.Civ.P. 25(d), Secretary Becerra is automatically substituted as a party to this action.

Social Security Act, codified at 42 U.S.C. §§ 1395-1395gg. The Centers for Medicare & Medicaid Services ("CMS") of the United States Department of Health and Human Services ("HHS") is responsible for administering the Medicare Program, which consists of four basic parts, Parts A through D. Part B of the Medicare Program ("Part B") authorizes payment for "medical and other health services" including certain out-patient prescription drugs. 42 U.S.C. § 1395k. This case concerns Part B because it involves the out-patient administration of a prescription cancer-treatment drug. Physicians who provide services under Part B ("providers") may submit claims to Medicare for reimbursement for the costs of purchasing and administering out-patient prescription drugs found to be "reasonable and necessary for the diagnosis and treatment of illness[.]" 42 U.S.C. § 1395y(a).

B. The Medicare Payment System and Appeals Process

The Part B reimbursement system is administered by CMS in conjunction with private contractors known as Medicare Administrative Contractors ("MACs"). See 42 U.S.C. § 1395kk-1. MACs typically authorize payment of claims immediately upon receipt of the claims, so long as such claims do not contain obvious irregularities. Later, post-payment audits may be conducted either by MACs or by independent auditors. See Medicare Program Integrity Manual, CMS Pub. No. 100-08, Ch. 3, § 3.2.2. If billing irregularities are discovered in a post-payment audit, overpayments are assessed and recouped from the provider. See 42

C.F.R. §§ 405.370, 405.371(a)(2). A provider who disagrees with an overpayment assessment is entitled to five levels of administrative review: (1) a redetermination by a MAC employee not involved in the initial overpayment determination, *see id.* §§ 405.940-405.958; (2) a reconsideration by a Qualified Independent Contractor ("QIC"), *see id.* §§ 405.960, 405.976(b); (3) a hearing before an Administrative Law Judge ("ALJ"), *see id.* §§ 405.1000, 405.1002(a); (4) de novo review by the Medicare Appeals Council (the "Council"),² either at the request of the provider, by referral from a MAC, or upon the Council's own motion, *see id.* §§ 405.1100, 405.1102(a), 405.1110; and (5) judicial review in federal court, *see* 42 U.S.C. § 405(g).

C. Factual and Procedural Background

Plaintiff, Dr. Ruth E. Kantor ("Dr. Kantor"), is a medical doctor practicing in oncology and internal medicine in Baltimore, Maryland. Between February 2010 and August 2012, Plaintiff purchased and administered seventeen doses of Avastin, an injectable cancer treatment drug, to her terminally ill cancer patient, Paulette D. Witherspoon. Dr. Kantor then submitted claims for reimbursement for such costs to Medicare, which totaled approximately fifty thousand dollars. Initially, the claims were approved and Dr. Kantor's expenses were reimbursed. It was

² The Council's decision becomes the Secretary's decision and is the final agency decision for purposes of judicial review. *See* 42 C.F.R. § 405.1136(d).

subsequently determined, however, during a post-payment audit that Dr. Kantor was not entitled to reimbursement for the funds that she had expended on Ms. Witherspoon's behalf. Disagreeing with this decision, Dr. Kantor initiated the five-level administrative appeals process, culminating in her filing of the instant complaint in this court requesting judicial review of the Secretary's decision. (ECF No. 1).

While the parties have not formally moved for summary judgment, the Secretary produced and filed the administrative record in this case on November 4, 2020. (See ECF Nos. 11-1 - 11-3). Because, as detailed below, the court may only consider the administrative record in making its determination in this case, *see Camp v. Pitts*, 411 U.S. 138, 142 (1973), the case is ripe for disposition and the court now rules on the basis of the administrative record alone. The arguments advanced by the parties in the context of the motion to dismiss for failure to exhaust administrative remedies in reality address the ultimate question, whether the agency's determination was arbitrary and capricious.

II. Judicial Review of the Secretary's Decision

The Medicare Act provides for judicial review of final decisions by the Secretary of Health and Human Services regarding benefits paid under Medicare Part B. 42 U.S.C. §§ 1395ff(a),(b). Review is to be based solely on the administrative record. 42 U.S.C. § 405(g) (incorporated by reference in 42 U.S.C. § 1395ff(b)(2)(a)). Review of the Secretary's decision is governed, moreover, by the Administrative Procedure Act, 5 U.S.C. §§ 701-706, which provides that the Agency's

decision will be set aside only if it found to be "arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with the law . . . or unsupported by substantial evidence." 5 U.S.C. § 706(2)(A),(E); *Natural Resources Defense Council v. U.S. Environmental Protection Agency*, 16 F.3d 1395, 1400 (4th Cir. 1993).

MacKenzie Med. Supply, Inc. v. Leavitt, 419 F. Supp. 2d 766, 770 (D.Md. 2006), *aff'd*, 506 F.3d 341 (4th Cir. 2007). "Because the facts are restricted to those in the administrative record, the court here is primarily concerned with issues of law." *Id.* "[I]t is the [c]ourt's role to 'determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did.'" *Abington Mem'l Hosp. v. Burwell*, 216 F. Supp. 3d 110, 129 (D.D.C. 2016) (quoting *Styrene Info. & Research Ctr., Inc. v. Sebelius*, 944 F.Supp.2d 71, 77 (D.D.C. 2013)). "In short, when a district court reviews agency action, it 'sits as an appellate tribunal, and [t]he entire case on review is a question of law.'" *Id.* (quoting *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001)).

In determining whether agency action is arbitrary and capricious, the reviewing court must "consider whether an agency's decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). At a minimum, the agency must have considered relevant

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