NOT FOR PUBLICATION

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MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

STEVEN BRUCE, Plaintiff-Appellant, v. ALEX M. AZAR II, Secretary of the U.S. Department of Health and Human Services; et al., Defendants-Appellees.	No. 19-17565 D.C. No. 4:18-cv-05022-HSG MEMORANDUM[*]

Appeal from the United States District Court
for the Northern District of California
Haywood S. Gilliam, Jr., District Judge, Presiding

Submitted October 15, 2020[**]
San Francisco, California

Before: McKEOWN and NGUYEN, Circuit Judges, and VITALIANO,[***] District Judge.

Steven Bruce appeals from the district court's orders granting motions to

[*] This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

[**] The panel unanimously concludes this case is suitable for decision without oral argument. *See* Fed. R. App. P. 34(a)(2).

[***] The Honorable Eric N. Vitaliano, United States District Judge for the Eastern District of New York, sitting by designation.

dismiss filed by Blue Shield, Envision, and the Department of Health and Human Services ("DHHS") and granting DHHS's summary judgment motion on the remaining claim against it. Bruce claims that DHHS's denial of coverage under Medicare Part D for Serostim—a drug he was prescribed to treat his lipodystrophy and wasting syndrome—was not supported by substantial evidence and violated the Fifth Amendment Due Process Clause and Section 504 of the Rehabilitation Act. The parties are familiar with the facts, so we do not repeat them here. We affirm.

The Medicare Appeals Council's decision that Serostim was not a covered Part D drug is supported by substantial evidence and not based on legal error. *See Magallanes v. Bowen*, 881 F.2d 747, 750 (9th Cir. 1989). For purposes of the Medicare Act, a "covered part D drug" includes "any use of a covered part D drug for a medically accepted indication." *See* 42 U.S.C. § 1395w-102(e)(1)(B). A "medically accepted indication" is, in turn, defined as "any use for a covered outpatient drug" which is approved by the FDA or supported by citations in one of three pharmaceutical compendia. *See id.* §§ 1396r-8(k)(6), 1396r-8(g)(1)(B)(i). Serostim is FDA-approved for wasting syndrome in individuals with HIV and short bowel syndrome. There is no evidence that any of the compendia list non-HIV-related wasting syndrome—the condition Bruce suffers from—as an approved use of Serostim. Because Bruce was not prescribed Serostim for a

"medically accepted indication," the prescribed Serostim does not satisfy the Medicare Act's definition of a "covered part D drug."

Bruce argues that a "medically accepted indication" may also be supported by peer reviewed medical literature. *See* 42 U.S.C. § 1395x(t)(2)(B). However, the broader definition of "medically accepted indication" contained in § 1395x(t)(2)(B) applies only to drugs used in anticancer chemotherapeutic regimens and thus is not applicable here. *See id.* § 1395x(t)(2)(A). Bruce's argument that he is entitled to a medical necessity exception pursuant to 42 C.F.R. § 423.578 also fails because this section does not "allow an enrollee to . . . request or be granted coverage for a prescription drug that does not meet the definition of a Part D drug." 42 C.F.R. § 423.578(e).

The district court lacked jurisdiction over Bruce's due process and Rehabilitation Act claims against DHHS under 42 U.S.C. § 405(h). That section, which "purports to make exclusive the judicial review method set forth in [42 U.S.C.] § 405(g)," *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 10 (2000), provides that "[n]o action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim *arising under* [the Medicare Act]," 42 U.S.C. § 405(h) (emphasis added). "[O]ur case law establishes that where, at bottom, a plaintiff is complaining about the denial of Medicare benefits—[such as]

drug benefits under Part D—the claim 'arises under' the Medicare Act." *Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1142–43 (9th Cir. 2010). Because Bruce's due process and Rehabilitation Act claims are, at bottom, about the denial of Medicare benefits, these claims "arise under" the Medicare Act and § 405(h) bars judicial review of them.

Bruce's claims against Envision and Blue Shield, the insurers that administered Bruce's Medicare Part D prescription drug plan, are also about the denial of Medicare benefits and arise under the Medicare Act. As such, those claims, too, are subject to 42 U.S.C. §§ 405(h) and (g) and related Medicare regulations. Pursuant to these statutes and regulations, Envision and Blue Shield were not properly named as defendants in this action. *See* 42 C.F.R. § 423.2136(d)(1) (providing that in a civil action seeking court review of a Medicare Appeals Council decision, the Secretary of DHHS is "*the* proper defendant" (emphasis added)); *Do Sung Uhm*, 620 F.3d at 1145 ("[Appellants] cannot circumvent § 405(h)'s requirements by suing [the Part D prescription drug provider].").

Finally, the district court did not abuse its discretion in denying Bruce's motion to supplement the administrative record. The administrative record is presumed to be complete, and Bruce did not present "clear evidence to the contrary" rebutting this presumption. *See In re United States*, 875 F.3d 1200, 1206

(9th Cir. 2017), *cert. granted, judgment vacated on other grounds*, 138 S. Ct. 443 (2017). Nor did Bruce demonstrate that any of the narrow exceptions allowing the reviewing court to consider extra-record evidence applied. *See San Luis & Delta–Mendota Water Auth. v. Locke*, 776 F.3d 971, 992–93 (9th Cir. 2014).

AFFIRMED.[1]

[1] Bruce's motions to take judicial notice (Dkt. 7) and supplement the record on appeal (Dkt. 29) are denied.