IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge Philip A. Brimmer

Civil Action No. 13-cv-02218-PAB

JANICE CIHAK,

Plaintiff,

v.

SYLVIA BURWELL, Secretary of Health and Human Services,

Defendant.

ORDER

This matter is before the Court on plaintiff Janice Cihak's complaint [Docket No. 1], filed on August 19, 2013. Plaintiff seeks review of the final decision of defendant Sylvia Burwell,[1] in her capacity as the Secretary of Health and Human Services (the "Secretary"), denying plaintiff's claim for Medicare Part D benefits under Title XVIII of the Social Security Act (the "Act"), 42 U.S.C. § 1395 *et seq*. The Court has jurisdiction to review the Secretary's final decision pursuant to 42 U.S.C. §§ 405(g), 1395ff(b).

I. BACKGROUND

A. Medicare and the Coverage Gap Discount Program

The Medicare statute, enacted in 1965, is a federal health insurance program primarily benefitting those 65 years of age or older. *See* Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (codified as amended at 42 U.S.C. §§ 1395 to

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[1]Pursuant to Rule 25(d) of the Federal Rules of Civil Procedure, Sylvia Burwell, who was sworn in as Secretary of Health and Human Services on June 9, 2014, is automatically substituted for Kathleen Sebelius as the defendant in this suit.

1395kkk-1). To be eligible, an individual must be (1) 65 years of age or older; (2) disabled and entitled to social security disability benefits; or (3) medically determined to have end stage renal (kidney) disease. 42 U.S.C. § 1395c. The Centers for Medicare and Medicaid Services ("CMS") is the agency within the Department of Health and Human Services charged with the administration of Medicare. *See Sw. Pharm. Solutions, Inc. v. Ctrs. for Medicare and Medicaid Servs.*, 718 F.3d 436, 439 (5th Cir. 2013). The Medicare program is divided into four major components – Parts A, B, C, and D. Part A of the program provides for hospital insurance services, including inpatient hospital services, post-hospital extended care services, home health services, and hospice care. 42 U.S.C. § 1395d(a). Part B is a voluntary program that provides supplemental benefits to Medicare participants to cover the costs of, among other things, home health services, physician services, and outpatient physical therapy services. 42 U.S.C. § 1395k. Part C, the "Medicare + Choice" (M+C) program, allows eligible participants to opt out of the traditional Part A fee-for-service system and instead obtain various benefits through Medical Advantage Organizations, which receive a fixed payment from the United States for each enrollee. 42 U.S.C. § 1395w-21. Part D of the program subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare beneficiaries. 42 U.S.C. §§ 1395w-101 *et seq*.

This appeal concerns the "Coverage Gap Discount Program" (the "discount program"), which was added to Medicare Part D by the Patient Protection and Affordable Care Act. 111 Pub. L. No. 148, 124 Stat. 119, 461 (2010). The discount program was enacted to reduce the expense for prescription medications for Medicare

enrollees who fall into Medicare's coverage gap.[2] The discount program provides that, for brand name prescription drugs to be covered under Medicare Part D, the drugs' manufacturers must enter into a written agreement to provide their brand name drugs at a fifty percent discount to enrollees who fall into the coverage gap. 42 U.S.C. §§ 1395w-114a(b), 1395w-153(a). To be eligible for a given plan year, the manufacturer must have entered into the discount agreement no later than January 30 of the previous year. 42 U.S.C. § 1395w-114a(b)(1)(C)(ii).

The discount program includes an exception (the "exception") that leaves open the possibility of Part D coverage for drugs whose manufacturer has not agreed to participate in the discount program where "the Secretary has made a determination that the availability of the drug is essential to the health of beneficiaries under [Part D.]" 42 U.S.C. § 1395w-153(c)(1).[3] In subsequently-issued regulations, the Secretary delegated the authority to determine whether a drug qualifies for the exception to CMS. *See* 42 C.F.R. § 423.2310(b).

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[2]The coverage gap, sometimes referred to as the "donut hole," applies to Medicare Part D enrollees whose annual expenses for prescription medications exceed the initial limit for Medicare Part D coverage, *see* 42 U.S.C. § 1395w-102(b)(3)(A), but fall short of the amount required to qualify for catastrophic coverage. *See* 42 U.S.C. § 1395w-102(b)(4)(B). When an enrollee falls into the coverage gap, he or she is required to pay 100% of the cost of the otherwise-covered drugs.

[3]§ 1860D-43(c)(1) of the Act.

B. Plaintiff's Application for Benefits

Plaintiff was born on April 9, 1945, and is 69 years old. R. at 147. Plaintiff suffers from severe arterial thrombosis,[4] a life-threatening condition that resulted in the loss of plaintiff's leg. *Id.* at 125. Plaintiff seeks coverage for a brand name anticoagulant called Iprivask.

Plaintiff's treaters have experimented with a series of anticoagulant medications, including aspirin, Lovenox, Coumadin, unfractionated heparin, and Arixtra (generic name fondaparinux), but those medications were either ineffective at managing plaintiff's condition or produced severe side effects. *Id.* at 125, 362-63. In particular, plaintiff expressed that she would rather die than experience the adverse effects of Arixtra. *Id.* at 363. For a time, plaintiff was taking the anticoagulant Refludan (generic name lepirudin), which she was tolerating well, but Refludan is no longer being manufactured. *Id.* at 125, 363. The remaining medication options have either been tried without success or are chemically similar to drugs that have been tried without success. *Id.* at 364-66.

On January 11, 2013, plaintiff requested that her prescription drug plan, SilverScript, grant an exception to cover Iprivask, which was not on SilverScript's list of covered drugs. R. at 325-29. In support of plaintiff's request, her physician, Dr. Kathryn Hassell, wrote a letter to SilverScript describing the severity of plaintiff's condition and her need for consistent anticoagulation treatment in order to "avoid significant complications including organ damage, amputation, prolonged hospitalization

[4]Thrombosis is "clotting within a blood vessel that may cause infarction of tissues supplied by the vessel." Stedman's Medial Dictionary thrombosis (27th ed. 2000).

and death." *Id.* at 329. SilverScript denied plaintiff's request on January 12, 2013, writing that it was unable to cover Iprivask because the drug's manufacturer had not agreed to participate in the discount program. *Id.* at 331. On January 16, 2013, Dr. Hassell requested that SilverScript reconsider its denial. *Id.* at 311-12, 318. SilverScript reaffirmed its denial of coverage on January 18, 2013, stating that it was unable to cover Iprivask. *Id.* at 320. On January 26, 2013, Maximus Federal Services ("Maximus"), an independent review entity, upheld SilverScript's denial of coverage on the grounds that plaintiff's plan with SilverScript does not cover drugs that do not qualify for Medicare Part D coverage. R. at 295-96. In response to Maximus' denial, Dr. Hassell, acting on plaintiff's behalf, requested an expedited hearing before an Administrative Law Judge ("ALJ"). R. at 293.

Following a hearing, the ALJ issued an order on February 8, 2013. R. at 124-134. The ALJ found that, if a Medicare Part D drug manufacturer does not sign an agreement to participate in the discount program, the drugs that it manufactures are not considered "Part D" drugs. R. at 132. Iprivask's manufacturer, Canyon Pharmaceuticals, did not sign such an agreement. *Id.* Therefore, Iprivask was not a Part D drug and not eligible to be used as an exception to SilverScript's formulary. *Id.* The ALJ held, however, that since the Secretary delegated her authority to ALJs to administer the nationwide hearing and appeals system for Medicare, *id.* at 133 (citing 70 Fed. Reg. 36386, 36387 (June 23, 2005)), the ALJ had the authority to decide whether a drug qualifies for the exception of § 1860D-43(c). *Id.* The ALJ further held that Iprivask qualified under the exception to the discount program in 42 C.F.R.

§ 423.578[5] because it was essential to plaintiff's health, and that Iprivask would therefore be considered a Part D drug in plaintiff's case. R. at 133. The ALJ ordered SilverScript to cover Iprivask under plaintiff's prescription drug plan. *Id.*

The Medicare Appeals Council (the "Council"), on its own motion, reviewed and reversed the ALJ's holding. R. at 4-5. The Council held that the Secretary delegated the authority to invoke the exception in § 1860D-43(c) to the CMS, not the ALJ. R. at 9-11 (citing 42 C.F.R. § 423.2310(b)). Pursuant to 42 C.F.R. § 423.2130, the Council's decision is the final decision of the Secretary.

Plaintiff appealed the Council's decision. The issue presented on appeal is whether the ALJ had the authority to invoke the exception in § 1860D-43(c) to find that a drug can be covered by Medicare Part D even where the manufacturer did not sign an agreement to participate in the discount program. Docket No. 23 at 12.

II. ANALYSIS

Once the Secretary has rendered a final decision on a Medicare claim, judicial review of that decision is available in the same manner as provided in 42 U.S.C. § 405(g) for old age and disability claims arising under Title II of the Social Security Act. *Heckler v. Ringer*, 466 U.S. 602, 605 (1984); 42 U.S.C. § 1395ff(b)(1)(A) (stating that "any individual dissatisfied with any initial determination under subsection (a)(1) of this section" is entitled to reconsideration, a hearing by the Secretary, and "to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g)").

[5]This section provides that a Part D plan sponsor must have a process to grant exceptions when a non-preferred drug for treatment of an enrollee's condition is medically necessary.

Under § 405(g), review of the Secretary's finding that a claimant is not entitled to Medicare benefits is limited to whether the Secretary's finding is supported by substantial evidence and not contrary to law. *Chipman v. Shalala*, 90 F.3d 421, 422 (10th Cir. 1996). The district court may not reverse the Secretary simply because the court may have reached a different result based on the record; the question instead is whether there is substantial evidence showing that the Secretary was justified in her decision. *See Andrade v. Sec'y of Health & Human Servs*., 985 F.2d 1045, 1047 (10th Cir. 1993). Substantial evidence is more than a mere scintilla and is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. *See Via Christi Reg'l Med. Center, Inc. v. Leavitt,* 509 F.3d 1259, 1271 (10th Cir. 2007).[6]

As noted above, the issue before the Court is whether the ALJ had the authority to find that Iprivask qualifies for the exception in § 1860D-43(a) even though Canyon Pharmaceuticals did not sign an agreement to participate in the discount program. The Court finds that the Secretary delegated the authority to determine whether a

[6]Pursuant to 42 U.S.C. § 1395w-22(g)(2), judicial review of the Secretary's final decision is available provided the amount in controversy is met. The amount in controversy required for district court review is $1,400. *See* 77 Fed. Reg. 59618-19 (Sept. 28, 2012) (setting the amount in controversy requirement for cases filed in 2013 at $1,400). Plaintiff states that the amount in controversy is met based on an estimated $4,500 monthly cost of Iprivask. *See* Docket No. 23 at 11 (assuming a dose of at least one vial per day). The Secretary responds that it is "unclear" whether the amount in controversy requirement is met because plaintiff's calculation is based on the market value of Iprivask, and not the costs that plaintiff could actually incur during a plan year. Docket No. 24 at 6. In an appeal of denial of prescription drug benefits, plaintiff is entitled to use the projected annual cost for a prescription drug. *See Southwest Pharm. Solutions, Inc. v. Centers for Medicare and Medicaid Servs.*, 718 F.3d 436, 446 n.6 (5th Cir. 2013). Given the stated cost of Iprivask ($150.00 per dose), as few as ten doses per year would exceed the $1,400 amount in controversy requirement.

prescription drug qualifies for the exception to CMS.[7] Plaintiff has failed to show any express or implied delegation of such authority to an ALJ.

The Council first noted that § 1860D-43(c)(1) refers to the Secretary making an exception based on the "health of beneficiaries," not "beneficiary." R. at 10 (citing 42 U.S.C. § 1395w-153(c)(1)). Because a determination based upon a group of "beneficiaries" is more appropriately determined by the CMS through its data collection capability as opposed to an ALJ reviewing a single beneficiary's claim, the Council believed that any delegation of such authority would more appropriately be made to the CMS rather than to an ALJ. However, this observation, by itself, does not answer the question as to whether the Secretary delegated such authority to the ALJ.

Second, the Council found that the regulation that the Secretary promulgated to implement the exception expressly delegated the exception-granting authority to CMS. *Id.* (citing 42 C.F.R. § 423.2310(b)).

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[7]In addition to finding that Iprivask qualifies as a Part D drug for plaintiff, the ALJ also found that Iprivask qualifies as an exception to SilverScript's formulary under 42 C.F.R. § 423.578. *See* R. at 133. The Council did not discuss this holding in its decision, *see id.* at 1-11, and plaintiff does not address it in her opening brief. *See generally* Docket No. 23. As noted above, § 423.578 governs the exception process that a prescription drug plan like SilverScript must put in place for drugs that are non-preferred drugs or not on the plan's formulary. Plans are required to have a process by which they can grant exceptions upon a determination that a non-formulary Part D drug is medically necessary. *See* 42 C.F.R. § 423.578(a). "Nothing in [§ 423.578]," however, "may be construed to allow an enrollee to use the exceptions processes set out in [§ 423.578] to request or be granted coverage for a prescription drug that does not meet the definition of a Part D drug." Because Iprivask was not a Part D drug, the Court finds that the ALJ did not have authority to find that Iprivask qualifies for an exception to SilverScript's formulary. *See Rickhoff v. U.S. Sec'y ex rel. Dep't of Health and Human Servs.*, 2012 WL 6177411 at *4 (D. Az. Dec. 11, 2012) (holding that a medicare enrollee cannot invoke the exception of § 423.578 to obtain coverage for a non-Part D drug).

The Court agrees with the Council that the Secretary delegated the authority to determine exceptions to CMS. The implementing regulation provides:

> (a) Covered Part D drug coverage requirement. Except as specified in paragraph (b) of this section, in order for coverage to be available under Medicare Part D for applicable drugs of a manufacturer, the manufacturer must do all of the following:
>
> > (1) Participate in the Discount Program.
> >
> > (2) Have entered into and have in effect an agreement described in [42 C.F.R. §] 423.2315(b).
> >
> > (3) Have entered into and have in effect, under terms and conditions specified by CMS, a contract with the TPA.
>
> (b) Exception to covered drug coverage requirement. Paragraph (a) of this section does not apply to an applicable drug *if CMS has made a determination* that the availability of the applicable drug is essential to the health of beneficiaries enrolled in Medicare Part D.

42 C.F.R. § 423.2310 (emphasis added). By its plain terms, § 423.2310(b) conditions exceptions to the requirements of § 423.2310(a) on a determination made by CMS. Plaintiff offers no contrary interpretation of § 423.2310, *see* Docket No. 23, and offers no other regulations that discusses exceptions to § 423.2310(a).

The ALJ based his authority to determine exceptions under § 1860D-43(c) on regulations by which the Secretary delegated her authority to administer the nationwide hearings and appeals system for the Medicare program to the Office of Medicare Hearings and Appeals. R. at 133 (citing 70 Fed. Reg. 36386, 36387 (June 23, 2005)). This regulation, however, applies only to the administration of an adjudicative system. *See* 70 Fed. Reg. at 36387. The ALJ cites no support for the Secretary's delegation of her authority under § 1860D-43(c) to make exceptions, which is not an adjudicative

function. Neither the ALJ nor plaintiff has identified a source of delegation to the ALJ here to have created an exception for Iprivask under § 1860D-43(c).

Finally, plaintiff argues that, because CMS declined to promulgate regulations that establish an administrative scheme by which enrollees could petition for coverage under the exception, "the reasonable conclusion is that [plaintiff's] avenue of redress was through the administrative hearing process." Docket No. 23 at 16. The Court disagrees. During the rulemaking process, CMS noted that it found it "highly unlikely that [CMS] will need to exercise" the authority to carve out exceptions, "given the strong participation by manufacturers in the Discount Program since 2011 and the likely availability of therapeutic alternatives for any Part D drugs." 77 Fed. Reg. 22072, 22083 (April 12, 2012). CMS's failure to use its authority either to carve out exceptions or to create an administrative scheme for enrollees to petition for exceptions does not, as plaintiff suggests, compel the conclusion that CMS intended to delegate its authority to ALJs to make exceptions on a case-by-case basis.

Because the ALJ did not have the authority to determine whether a prescription drug qualifies for the exception in § 1860D-43(c), the ALJ did not have the authority to order SilverScript to cover Iprivask.

III. CONCLUSION

For the foregoing reasons, it is

ORDERED that the decision of the Secretary that plaintiff is not entitled to coverage for Iprivask under Medicare Part D is **AFFIRMED**.

DATED March 30, 2015.

BY THE COURT:

s/Philip A. Brimmer
PHILIP A. BRIMMER
United States District Judge