IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

Alexandria Division

LISA ROEDER,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 1:15-cv-01194
	)	
SYLVIA MATHEWS BURWELL,	)	
	)	
Defendant.	)	
	)	

MEMORANDUM OPINION

THIS MATTER comes before the Court on Plaintiff's and Defendant's cross Motions for Summary Judgment.

Plaintiff Lisa Roeder, Executor of the Estate of William F. Roeder, Jr., seeks Medicare Part D coverage for mycophenolate mofetil, brand name CellCept. Mr. Roeder took CellCept prior to his death to treat systemic sclerosis with interstitial lung disease and pulmonary fibrosis. By decision of the Medicare Appeals Council ("MAC"), the Secretary determined that Plaintiff's Medicare Part D plan was neither required nor permitted to cover his use of CellCept. Coverage was denied because the Medicare statute, regulations, and manual instructions do not recognize CellCept as a covered Part D drug as used by Mr. Roeder. Mr. Roeder's "off-label" use was not for a "medically accepted indication." CellCept as prescribed to Mr.

Roeder is not a covered Part D drug.

Plaintiff acknowledges that Mr. Roeder's CellCept prescription was neither written nor used for a "medically accepted indication." Plaintiff argues that Medicare must nonetheless cover the prescription because the drug is approved for sale by the Food and Drug Administration ("FDA"), and because his prescribing physician found it effective treatment for his condition.

Mr. Roeder was a Medicare beneficiary enrolled in Medicare Part D as a member of AARP MedicareRx Preferred, a prescription drug plan offered by United Healthcare Insurance Company ("United Healthcare"). His treating physician diagnosed him with systemic sclerosis with interstitial lung disease, and prescribed mycophenolate mofetil (the generic of CellCept).

Mr. Roeder sought authorization from United Healthcare for the CellCept prescription. On June 27, 2013, upon expedited redetermination, the plan sponsor confirmed its initial denial because the drug was "not supported by the FDA or one of the Medicare approved references for treating [plaintiff's] medical conditions."

Plaintiff sought reconsideration of this determination from Maximus, a Medicare Part D IRE. Maximus affirmed United Healthcare's coverage denial based on Mr. Roeder's prescribed use of CellCept not qualifying as a "medically accepted

indication," finding it thus "d[id] not meet the definition of a Medicare Part D drug." For the same reason, Maximus also found that Mr. Roeder was not entitled to an "exceptions request based on medical necessity."

Mr. Roeder appealed the Maximus decision to an ALJ. After a hearing in which Plaintiff's counsel and a United Healthcare representative participated, the ALJ issued a "Fully Favorable" decision to Plaintiff. The ALJ noted that the Medicare statute and regulations require a drug to be used for its FDA-approved use or a use supported by citation in the compendia to be a covered Part D drug. Nevertheless, because CellCept became the "standard of care for the treatment of scleroderma lung disease," and based on the "evidence of 9 separate studies showing that the drug has been used successfully for the Beneficiary's condition," he concluded that "the treatment is covered due to the circumstances presented in this case."

The MAC decided on its own motion to review the ALJ's decision "because there [wa]s an error of law material to the outcome of the claim." The MAC reversed the ALJ's decision and held that Medicare did not cover plaintiff's CellCept prescription because the plain language of the statute, implementing regulations, and manual provision limit the definition of "medically accepted indication" to a use approved by the FDA or supported by one or more citations in the

compendia, and the prescription here was not for a "medically accepted indication."[1] In so ruling, the MAC noted that "the appropriate inquiry in this case was not whether [CellCept] was medically reasonable and necessary for the treatment of the enrollee's condition, but whether [CellCept] met the definition of a Part D drug, i.e., whether it is prescribed for a 'medically accepted indication.'" The MAC also ruled that Mr. Roeder did not qualify for a formulary exception because that process "may not be invoked to cover a drug that is not otherwise within the definition of a Part D drug."[2]

Because the crux of Plaintiff's argument is that the Secretary improperly interpreted the relevant statutory language to deny his request for Part D coverage, this Court must apply the framework set forth in Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.[3] Under Chevron, the Court must employ a two-step analysis:

> First, applying the ordinary tools of statutory construction, the court must determine whether Congress has directly spoken to the precise question at

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[1] See Medicare Prescription Drug Benefit Manual, Chapter 6, section 10, available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/chapter6.pdf (last visited Feb. 26, 2016).

[2] Id. (citing 42 C.F.R. § 423.578(e)).

[3] 467 U.S. 837 (1984). See Md. Dep't of Health & Mental Hygiene v. Ctrs. for Medicare & Medicaid Servs., 542 F.3d 424, 428 (4th Cir. 2008) (when the challenged CMS action "depends on construction of the Medicaid statute, we view that administrative interpretation "through the lens of Chevron[.]").

issue.

> If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. But if the statute is silent of ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.[4]

The issue is whether the definition of "covered part D drug," as set forth in Section 102(e), is limited to a "medically accepted indication"—either by the plain terms of the statute, or, to the extent the Court deems the statute ambiguous, by a permissible interpretation the Secretary expressed through adjudication of this case and regulation duly published through notice-and-comment rulemaking. Plaintiff acknowledges that Mr. Roeder's CellCept prescription was not made for a "medically accepted indication" within the meaning of that provision, as the prescription was neither for an "on label" use approved by the FDA, nor for a non-cancer "off-label" use that is supported by citation in a qualifying drug compendia. Thus, the issues raised by this case are purely legal and of statutory construction.

Summary judgment must be entered in favor of the Secretary for three reasons. First, the plain language of Section 102(e)(1) unambiguously limits Part D coverage to drugs

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[4] City of Arlington v. FCC, --- U.S. ---, 133 S.Ct. 1863, 1868 (2013) (internal citations omitted).

prescribed for a "medically accepted indication," which Plaintiff admits is a condition that Mr. Roeder's CellCept prescription did not satisfy. Second, even if the Court were to find the statute ambiguous on this question, the Secretary's interpretation of the statute is entitled to substantial deference and definitively resolves the question. Third, Plaintiff's claim to a drug formulary exception under 42 C.F.R. § 423.578 must fail: the same reasons that foreclose his interpretation of the statute bar his construction of this regulatory exception.

When interpreting a statute, it is well-settled that the first step is "to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case."[5] This inquiry is conducted "by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole."[6] Where "the statutory language is unambiguous and the statutory scheme is coherent and consistent," the "inquiry must cease" at this step.[7]

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[5] Robinson v. Shell Oil Co., 519 U.S. 337, 340 (1997).

[6] Robinson, 519 U.S. at 341; King v. Burwell, --- U.S.---, 135 S.Ct. 2480, 2489 (2015) (statutory provisions must be read "'in their context and with a view to their place in the overall statutory scheme'") (quoting FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000)).

[7] Robinson, 519 U.S. at 340 (internal citation omitted); see Chevron, 467 U.S. at 842-43.

The Court need look no further than the plain language of Section 102(e)(1), including its embedded cross-references, to uphold the Secretary's determination that Mr. Roeder's CellCept prescription was not, as required under the statute, for a "medically accepted indication."[8] The language, context, and structure of Section 102(e)(1) compel the conclusion that Part D coverage is unambiguously limited to drugs prescribed for a "medically accepted indication."

When the components of Section 102(e)(1) are read together—as they must be—it is clear that the "medically accepted indication" requirement incorporated by that provision is definitional (as opposed to merely illustrative, as Plaintiff would have it). Here is the language:

> **(e) Covered part D drug defined**
> (1) In general
> Except as provided in this subsection, for purposes of this part, the term "covered part D drug" means—
> (a) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1396r-8(k)(2) of this title; or
> (b) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section

[8] Five district courts reached the same conclusion in recent years. See Broome v. Burwell, 2015 WL 1526532 (D. Or. April 1, 2015); Diamond v. Sec'y of Health & Human Servs., 2015 WL 367010 (N.D. Ohio Jan. 27, 2015); Nievod v. Sebelius, 2013 WL 503089 (N.D. Cal. Feb. 8, 2013); Rickhoff v. Sec'y of Health & Human Servs., 2012 WL 6177411 (D. Ariz. Dec. 11, 2012); Kilmer v. Sec'y of Health & Human Servs., 609 F. Supp. 2d 750 (S.D. Ohio 2009). But see Layzer v. Leavitt, 770 F. Supp. 2d 579 (S.D.N.Y. 2011).

> and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary), and such term includes a vaccine licensed under section 262 of this title (and, for vaccines administered on or after January 1, 2008, its administration) and any use of a covered part D drug for a medically accepted indication (as defined in paragraph (4)).[9]

While subparagraphs (A) and (B) are separated by the disjunctive term "or," the medically accepted indication requirement in the third paragraph is introduced by the phrase "and such term includes . . . ." As one district court explained:

> The use of the conjunctive 'and' connotes that the third paragraph was intended by Congress to impose *additional* conditions on the two preceding paragraphs, while the use of 'such term' is intended to refer back to the term 'covered Part D drug.' Thus, taken together, the provisions of the third paragraph logically convey that the medically accepted indication requirement applies generally *and in addition to* the provisions of subsections (A) and (B).[10]

Another court summarized this common-sense construction similarly:

> [T]he statute provides in (A) two initial conditions that define a covered part D drug under that subparagraph: one, that the drug that may be dispensed only upon a prescription, and two, that the drug is also described in select provisions of 42 U.S.C. § 1396r-8(k)(2). . . . The last paragraph of § 1395w-102(e)(1) then adds a third condition, specifically that any use of a drug (a drug that satisfies the first two requirements for a covered part D drug) be for a medically accepted indication.

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[9] 42 U.S.C. § 1395w-102(e)(1) (emphasis added).

[10] Nievod v. Sebellius, 2013 WL 503089, at *7 (N.D. Cal. Feb. 8, 2013) (emphasis in original).

> To read the statute otherwise would be to ignore the statute's use of the language 'such term' in the clause 'and such term includes . . . any use of a covered part D drug for a medically accepted indication . . . .' 'Such term' refers back to 'the term "covered part D drug."' The specific reference is to covered part D drug, which means that the statutory scheme provides that the term *means* condition one (prescribed drug) and condition two (described-in-another-statute drug) and *includes* condition three (use is for medically accepted indication).[11]

These interpretations from the Northern District of California and the Southern District of Ohio are echoed in decisions from the District of Oregon, the Northern District of Ohio, and the District of Arizona.[12]

As Nievod and Broome recognize, through their respective cross-references to Section 1396r-8(k)(2), Subparagraphs (A) and (B) of Section 102(e)(1) themselves incorporate the requirement that a "covered part D drug" be prescribed for a "medically accepted indication." Nievod held,

> Stated another way, all of the drugs identified in the definition of a covered Part D drug must, by definition, satisfy the medically accepted indication requirement . . . . Consequently, it would be incongruous to construe section 1395w-102(e)'s reference to 'any use of a covered Part D drug for a

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[11] Kilmer v. Leavitt, 609 F. Supp. 2d 750, 753-54 (S.D. Ohio 2009) (quoting 42 U.S.C.A. § 1395w- 102(e)(1)).

[12] See Broome v. Burwell, 2015 WL 1526532 (D. Or. April 1, 2015) (following Nievod's reasoning and analysis); Diamond v. Sec'y of Health & Human Servs., 2015 WL 367010, at *5 (N.D. Ohio Jan. 27, 2015) ("The term 'medically accepted indication' is one element of the definition of a 'covered part D drug.'"); Rickhoff v. Sec'y of Health and Human Servs., 2012 WL 6177411, at *1 (D. Ariz. Dec. 11, 2012) ("To qualify as a covered Part D drug, a drug must be used for a 'medically accepted indication.'").

> medically accepted indication' as anything other than a specific circumscription on the definition of a covered Part D drug.[13]

The statutory language related to vaccines in the third paragraph of § 1395w-102(e)(1) further supports the Secretary's position that the phrase "and such term includes" is definitional. Because vaccines are specifically excluded from the Section 102(e)(1)(B) definition of biological products, Congress' re-inclusion of them through the "includes" term demonstrates that "includes" was meant to be definitional, not illustrative.[14] A vaccine cannot "illustrate" Subsection 102(e)(1)(B)'s definition of biological products. Vaccines are, in fact, specifically excluded from that definition by Subsection 102(e)(1)(B). By extension, because the "vaccine" portion of the "includes" clause cannot be merely illustrative.

In 2008 Congress partially amended the Part D statute, and in particular Section 102(e)(1), to replace the cross-referenced definition of "medically accepted indication"—which had been to the Medicaid definition for all drug uses—with a more expansive definition (the "Medicare Part B" definition) with respect to Part D drugs used in anti-cancer chemotherapeutic regimes (and

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[13] 2013 WL 503089, at *7; see also Broome, 2015 WL 1526532, at *3.

[14] Nievod, 2013 WL 503089, at *8. 42 U.S.C. § 1396r-8(2)(B), cross-referenced in § 1395w-102(e)(1)(B), reads in relevant part: "the term 'covered outpatient drug' means - . . . a biological product, *other than a vaccine*" (emphasis added.)

such drug uses only).[15] Thus, when Congress revised the statute in this manner, it viewed "medically accepted indication" as a limit on coverage: there would have been no need to broaden the more limited compendia requirement for anti-cancer drug uses if there were no "medically accepted indication" requirement in the first place.[16]

The "fact that Congress provided a detailed framework and different definitions for 'medically accepted indication' depending on the nature of the drug use," further underscores that this term is definitional and restrictive, and not (as plaintiff would have it) merely illustrative.[17] As Nievod explained, to hold otherwise would read the "medically accepted indication" requirement out of the statute, in contravention of the "'fundamental rule of statutory construction that [a court] should avoid an interpretation of a statute that renders any part of it superfluous and does not give effect to all of the

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[15] See Pub. L. No. 110- 275, § 182, 122 Stat. 2494, 2583 (2008).
[16] Cf. Loving v. United States, 517 U.S. 748, 770 (1996) (quoting Red Lion Broadcasting Co v. FCC, 395 U.S. 367, 380-81 (1969)) (stating that subsequent legislation should be given "great weight" in interpreting an earlier statute); Stone v. INS, 514 U.S. 386, 397 (1995) ("When Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect."); Brown v. Thompson, 374 F.3d 253, 260 (4th Cir. 2004) (similar); see also Kilmer, 609 F.Supp.2d at 751, n.1 (recognizing MIPPA passage "lend[s] some limited support" to Secretary's argument).
[17] Nievod, 2013 WL 503089, at *9.

words used by Congress.'"[18]

The more expansive "Medicare Part B" definition of "medically accepted indication" that Congress extended in 2008 to Part D drugs prescribed as part of an anti-cancer chemotherapeutic regimen existed long before Congress enacted Part D. In the very same legislation in which Congress defined medically accepted indication in Medicare Part B to include uses supported by peer-review literature, Congress intentionally removed a similar reference to peer-review literature from the definition of "medically accepted indication" used in the Medicaid statute, § 1396r-8(k)(6).[19] Later, when Congress enacted Part D, it chose to use the more restrictive definition for purposes of that program. Thus, had Congress wanted to more broadly define a covered Part D drug to include uses supported by peer-reviewed literature, as well as uses supported by the compendia, it could have referenced the Medicare Part B definition of "medically accepted indication." Instead, in creating Part D, Congress chose to define "medically accepted indication" as it did for Medicaid, which a decade earlier it

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[18] Id. (quoting Center for Biological Diversity v. Salazar, 695 F.3d 893, 903 (9th Cir. 2012); see also Burlington N. and Santa Fe R.R. Co. v. White, 548 U.S. 53, 63, (2006) ("We normally presume that, where words differ as they differ here, Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (internal quotations and citation omitted).

[19] See Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66 (1993), §§ 13553(b); 13602(a)(1).

had specifically limited to off-label uses supported by compendia citations. Congress plainly knew how to draft a statute that would expressly include a broader definition of "medically accepted indication," but it chose not to do so for Part D.

The plain language of Section 102(e)(1) limits Part D coverage to drugs prescribed for a "medically accepted indication." Plaintiff admits that Mr. Roeder's CellCept prescription did not satisfy that condition. Even if the statute were ambiguous, the Secretary's interpretation of the statute is entitled to substantial deference. Summary judgment must be entered in favor of the Defendant.

An appropriate order shall issue.

Claude M. Hilton
CLAUDE M. HILTON
UNITED STATES DISTRICT JUDGE

Alexandria, Virginia
June 21, 2016