

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-12-1470

In the case of

Claim for

L.P.
(Appellant)

Prescription Drug Benefits
(Part D)

(Enrollee)

(HIC Number)

Health Net/Health Net
Seniority Plus
(Part D Sponsor/Part D Plan)

(ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated February 7, 2012, which concerned the enrollee's request for Medicare Part D coverage of the compounded medications diclofenac and liothyronine, for the dates of service between February 21, 2011 and April 22, 2011.¹ The ALJ denied coverage, finding that the Part D plan (PDP or plan) was not required to cover the enrollee's prescription for these compounded drugs because they were compounded from bulk pharmaceutical chemical (BPC) powders, which are not reviewed and approved for safety and efficacy by the FDA and therefore do not meet the definition of a covered Part D drug. Dec. at 4. The regulations at 42 C.F.R. § 423.2100 *et seq.* provide that an enrollee who is dissatisfied with an ALJ hearing decision concerning Medicare Part D prescription drug benefits may request that the Medicare Appeals Council (Council) review the ALJ's decision.

¹ Appended to the ALJ's decision is a list of seven ALJ Appeal Numbers associated with the enrollee's claims for dates of service ranging from January 5, 2011 to July 20, 2011. The dates of service that were before the ALJ and specifically addressed in the ALJ's decision, February 21, 2011 to April 22, 2011, are associated with ALJ Appeal Number ****. The enrollee listed all seven ALJ Appeal Numbers in her request for review, apparently to conform to the ALJ's list of ALJ Appeal Numbers. However, the only dates of service addressed by the ALJ and now before the Council are February 21, 2011 to April 22, 2011.

The Council reviews the ALJ's decision *de novo*. 42 C.F.R. §§ 423.2100(b), 423.2108(a). The Council will limit its review of the ALJ's action to the exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. 42 C.F.R. § 423.2112(c).

The request for review, dated April 4, 2012, and supplemental statement, dated April 26, 2012, are admitted into the record as exhibits (Exh.) MAC-1 and MAC-2, respectively. As set forth below, the Council adopts the ALJ's decision.

BACKGROUND

The enrollee has hypothyroidism. See Exh. MAC-1; see also Hearing CD. She seeks coverage for the compounded medications, diclofenac and liothyronine, to treat her thyroid condition.

The enrollee's plan, Health Net Seniority Plus, denied coverage for diclofenac and liothyronine because these drugs are "excluded from coverage under Medicare Part D." See, e.g., Exh. 3 at 8. On redetermination, the plan stated that "Section 1927(d)(2) of the Social Security Act (the Act) permits the exclusion of certain drugs, classes of drugs, or their medical uses from coverage under Medicare Part D" and that diclofenac and liothyronine were excluded by Medicare regulations and were not included in Medicare Part D basic coverage. See, e.g., Exh. 4, at 27.

Upon request for reconsideration, the Independent Review Entity (IRE), Maximus, likewise determined that the enrollee's plan was not required to provide coverage for diclofenac and liothyronine. Exh. 5 at 1. Maximus determined that diclofenac and liothyronine were compounds that contained bulk powder and that the National Drug Code (NDC) for diclofenac (NDC #62991-2024-03) and for liothyronine (NDC #38779-0031-06) were on a Centers for Medicare and Medicaid Services (CMS) list of bulk powder products. *Id.* at 2-3. The IRE stated that "bulk powders used in pharmacy compounding are not reviewed and approved for safety and efficacy by the FDA and therefore do not meet the definition of a covered Part D drug." *Id.*

The enrollee then requested an ALJ hearing. The ALJ held a telephonic hearing on December 20, 2011. The enrollee and her son testified. The plan had a representative who testified during the hearing. Hearing CD. Subsequently, the ALJ issued an unfavorable decision, finding that the plan is not required

to cover the enrollee's prescription for diclofenac and liothyronine. Dec. at 4.

In reaching the conclusion that Part D does not cover diclofenac and liothyronine, the ALJ stated that:

Medicare requires a drug to be approved for safety and efficacy by the FDA. Bulk powders used in pharmacy compounding are not reviewed and approved for safety and efficacy by the FDA and therefore do not meet the definition of a covered [Part D] drug.

Although Diclofenac compound, and LioThyronine compound may be medically necessary, they are not FDA approved. The appellant's evidence of coverage clearly denies coverage for drugs which are not FDA approved.

Dec. at 4.

In her request for review, the enrollee asks why Medicare would pay for a doctor and then not follow the doctor's advice, in the form of an effective prescription. Exh. MAC-1. The enrollee also believes that the FDA should be concerned with the efficacy of a drug instead of the form of a drug, or how a drug is delivered. The final statement that the enrollee makes in her request for review is that the plan's "coverage decisions are advertised one way and actually made in another." *Id.* In her supplemental statement, the enrollee asserts that the active ingredients in the compounded drugs at issue are FDA approved. The enrollee contends that, because the active ingredients are FDA-approved, the compounded drugs are subject to Part D coverage. Exh. MAC-2.

AUTHORITIES

Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) established the Voluntary Medicare Prescription Drug Benefit Program (Medicare Part D), to be effective January 1, 2006. Implementing regulations were issued on January 28, 2005, codified at 42 C.F.R. part 423, and effective March 22, 2005. As of January 1, 2006, enrollees were eligible to receive drug benefits under a PDP in which they were enrolled. 70 Fed. Reg. 4194 (Jan. 28, 2005).

Section 1860D-2(e)(1) of the Social Security Act (Act) defines the term "covered Part D drug" as "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 1927(k)(2)" of the Act, "and any use of a covered Part D drug for a medically accepted indication (as defined in section 1927(k)(6))." Section 1927(k)(2)(A)(i) of the Act defines a "covered part D drug" as a drug that may be dispensed only upon a prescription and which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act, or which is approved under section 505(j) of such Act.

The implementing regulations in 42 C.F.R. part 423 mirror the language of the Act. Specifically, the regulations at 42 C.F.R. § 423.100 define the term "Part D drug" as-

(1) Unless excluded under paragraph (2) of this definition, any of the following if used for a medically accepted indication (as defined in section 1927(k)(6) of the Act)-

(i) A drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act;

. . .

CMS has stated that compounded products as a whole do not satisfy the definition of a "Part D drug." See Medicare Prescription Drug Benefit Manual (PDBM), CMS Pub. 100-18, Chapter 6, § 10.4.

The regulations at 42 C.F.R. § 423.578 implement the Part D exceptions process. Limitations to the exceptions process are found at 42 C.F.R § 423.578(e) which provides: "Nothing in this section may be construed to allow an enrollee to use the exceptions process set out in this section to request or be granted coverage for a prescription drug that does not meet the definition of a Part D drug."

DISCUSSION

The Council does not question the treating physician's opinion that the enrollee benefits from using compounded diclofenac and liothyronine to treat the enrollee's hypothyroidism. However, the Council cannot circumvent the applicable law which does not allow for Part D coverage of the compounded drugs at issue

because compounded drugs made from bulk pharmaceutical chemical powders are excluded from the Part D drug benefit. The Council also notes that the FDA does consider the efficacy of a drug in determining whether it will approve a drug for a medical condition or diagnosis. However, the efficacy of a drug is only one factor that the FDA considers when determining whether a drug will be approved. As for the enrollee's complaint about the manner in which the plan "advertises" the plan benefits, we can only make a decision on the coverage question before us. The Council has the authority to determine whether Medicare covers a Part D drug and whether the plan's Evidence of Coverage (EOC) provides coverage for a Part D drug as an enhanced benefit. In the instant case, we agree with the plan that diclofenac and liothyronine are specifically excluded from Part D coverage because they are compounded drugs made from bulk powders.

The enrollee argues that the compounded drugs at issue, diclofenac and liothyronine, meet the definition of Medicare Part D drugs because the active ingredient in each drug is an FDA-approved substance and therefore the compounded drugs should be covered by the plan. Exhs. MAC-2. The statute and regulations make clear that the definition of a Part D drug, for the purposes of Medicare prescription drug plan coverage, includes only prescription drugs that are FDA-approved *under sections 505, 505j, or 507 of the Food Drug and Cosmetic Act*, or are exempt from the FDA approval process through a "grandfathering" provision. Drugs made from bulk pharmaceutical powders are not subject to the FDA approval processes of these particular sections. Thus, they are not covered by Medicare Part D even if they serve a useful purpose for a Medicare beneficiary who cannot take an FDA-approved drug for medical reasons or who has found FDA-approved drugs ineffective. Under section 1927(k)(2)(A) of the Act, Congress limited coverage under Part D to drugs which are approved by the FDA under the three limited sections of the Food, Drug and Cosmetic Act, as well as to certain "grandfathered" (pre-1962) drugs (subsection (k)(2)(A)(ii)) for which there is a "compelling justification for its medical need" subject to the Secretary's actions (subsection (k)(2)(A)(iii)).

The FDA recognizes that some traditional compounded prescription drug products are beneficial. For purposes of Part D coverage, CMS has stated that compounded products as a whole do not satisfy the definition of a "Part D drug" and are thus not covered by Medicare Part D even if the compounded drugs are

available through a pharmacy. See Medicare Prescription Drug Benefit Manual (PDBM) (Pub. 100-18), Ch. 6, § 10.4.

In a letter dated December 9, 2008, to all PDP sponsors, CMS issued an update on National Drug Coverage. That document clarified that subcategory 203 (bulk pharmaceutical drugs), a specific subcategory of compounded pharmaceutical drugs, may not be covered as an enhanced benefit by Part D PDPs. *Id.* The letter stated, “[b]ulk products are not covered under Part D because they are not prescription drug products that are approved under sections 505, 505(j), or 507 of the Federal Food Drug and Cosmetic Act.” *Id.* at 27. Effective February 1, 2009, CMS reiterated that position and edited the coding system to “reject” codes for payment of drugs made from bulk pharmaceutical powders.

The Council notes that CMS’ declaration does not mean that the FDA has determined that compounded drugs made from bulk powders are unsafe or that they are not useful. CMS has determined only that extemporaneous compounds made from bulk powders in the compounding process are not approved drugs for the purposes of Medicare Part D because they are not prescription drug products approved under sections 505, 505(j), and 507 of the Food, Drug, and Cosmetics Act. Nor do they satisfy the definition of a Part D drug under section 1927(k)(2)(A) of the Act. Therefore, notwithstanding the enrollee’s assertion that the active ingredients of diclofenac and liothyronine may be FDA approved, the compounded drugs are not covered Part D Drugs because they are prepared from bulk pharmaceutical powders not approved by the FDA under the designated sections.

DECISION

The adopts the ALJ’s decision that diclofenac and liothyronine are not covered by Medicare Part D, and the Part D plan is not required to cover or pay for diclofenac and liothyronine.

MEDICARE APPEALS COUNCIL

/s/ Susan S. Yim
Administrative Appeals Judge

Date: May 6, 2014