DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-15-132

In the case of	**Claim for**
A.M. (Appellant)	Prescription Drug Benefits (Part D)
**** (Enrollee)	**** (HIC Number)
WellCare Classic (WellCare Prescription Insurance, Inc.) (Part D Plan)	**** (ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision unfavorable to the appellant enrollee, dated September 30, 2014. There, the ALJ denied the appellant's request that her Medicare Part D Plan, WellCare Classic, provide coverage for her prescribed Opium Tincture. The ALJ based that decision on a finding that Opium Tincture did not meet the definition of a Medicare Part D drug. The appellant has asked the Medicare Appeals Council (Council) to review this action.

The Council reviews the ALJ's decision *de novo*. 42 C.F.R. § 405.1108(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. § 405.1112(c).

The Council admits the appellant's request for review, filed by her representative on December 2, 2014, into the administrative record as Exhibit (Exh.) MAC-1. The appellant also made multiple procedural filings, including requests for an extension of time and a copy of the administrative record. The Council granted these requests and provided a copy of the record, with the hearing recording, to the appellant on January 5, 2014, and January 15, 2014. The appellant then filed a supplementary submission on February 20, 2015. The Council admits the

appellant's filings and the Council's interim correspondence into the record as Exhs. MAC-2 through MAC-8. The Council denies the appellant's preliminary motion for redaction of the ALJ's decision for purported violations of the Health Insurance Portability and Accountability Act (HIPAA) of 1996. *See* Exh. MAC-1, at 5-6.

As set forth below, the Council reverses the ALJ's decision.

BACKGROUND

The appellant's medical history, in relevant part, is significant for diarrhea and cramping secondary to irritable bowel syndrome (IBS). Dec. at 8; Exh. 2, at 19. The treating physician prescribed Opium Tincture 10 mg/ml 1%, 7 drops by mouth each morning, to control diarrhea. *Id.* at 9; Exh. 2, at 8-9.

On February 28, 2014, the plan denied the request initially, stating that the record did not indicate that the appellant had tried at least two formulary alternatives. Dec. at 9; Exh. 2, at 11. The appellant appealed, arguing that she had tried Lomotil, Bentyl, and Librax without benefit. *Id.*; Exh. 2, at 17. On March 10, 2014, the plan issued a favorable decision, approving Opium Tincture 10 mg/ml, from February 28, 2014 "until further notice," also stating that the approval was "subject to coverage limitations defined by your benefit." Exh. 2, at 39.

On April 8, 2014, the plan then issued an unfavorable redetermination, denying coverage of the Opium Tincture and stating that "[t]he current authorization is set to expire on 06/12/2014; this will then be a non-covered benefit." Dec. at 9; Exh. 2, at 51-53. In relevant part, the plan stated that Opium Tincture was not an FDA-approved drug, did not fall within the definition of a Part D drug, and was therefore not eligible for coverage under Medicare Part D. Exh. 2, at 51. On April 18, 2014, the Independent Review Entity affirmed the denial on reconsideration, stating that the Opium Tincture was not on the plan's formulary and was not FDA approved. Exh. 2, at 69-71.

On September 4, 2014, the ALJ conducted a telephone hearing, at which representatives for the appellant and the plan appeared. Dec. at 2. In the ensuing unfavorable decision, the ALJ denied coverage of the Opium Tincture, reasoning that –

> Appellant argues that Opium Tincture is a grandfathered drug as defined by Act § 1927(k)(2)(A)(ii). To that end, Appellant relies [on] the arguments set forth in *In the case of V.B.M.*, issued by the Medicare Appeals Council (MAC). In *V.B.M.*, the Council decided not to review or reverse the ALJ's decision as requested by the QIC. In its discussion, the MAC states that 'the FDA should be making decisions on the grandfathered status of marketed drugs rather than an ALJ.' Consequently, Appellant has not met its burden of proof that jurisdiction of this matter is properly at issue and that Opium Tincture is in-fact a grandfathered drug.
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> Further, the record demonstrates that the requirements for an exception to the formulary exclusion have not been met because Opium Tincture is not eligible for coverage.
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> Following a complete review of the record, including the arguments and testimony provided at the hearing, Medicare coverage cannot be allowed for the Opium Tincture at issue here as there is no FDA or Non-FDA (off-label) indication for use of opium tincture. As such, although the drug may provide beneficial relief to the Appellant's symptoms, it does not meet the definition of a covered Medicare Part D drug. The Part D Plan is not required to allow coverage for the requested Opium Tincture.

Dec. at 9. Under Conclusions of Law, the ALJ stated that the plan was not required to cover the Opium Tincture "because it is not eligible for coverage under the Medicare Part D benefit." *Id.* at 10.

By memorandum brief, dated December 2, 2014, with multiple attachments, the appellant requests Council review. Exh. MAC-1. In this filing, the appellant presents multiple contentions of ALJ error, including Constitutional Due Process, "medical indications" for the appellant's use of Opium Tincture, and the ALJ's failure to take judicial notice of the Council's previous decision, *In the Case of V.B.M. Id., passim*. Generally, however, the appellant's primary and repeated argument is that Opium Tincture is "grandfathered" into Medicare Part D coverage under section 1927(k)(2)(A)(ii) of the Act. Exh. MAC-1, at 9-16; Exh. MAC-8, at 1-2. Because the Council agrees with the

appellant on this issue, the Council need not and does not address the appellant's remaining contentions.

APPLICABLE LEGAL 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 (eff. March 22, 2005). As of January 1, 2006, enrollees were eligible to receive drug benefits under a plan in which they were enrolled. 70 Fed. Reg. 4194 (Jan. 28, 2005).

The Social Security 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 1860D-2(e)(1) of the Act. Section 1927(k)(2)(A)(i) of the Act defines a "covered part D drug" as a drug dispensed only on prescription and 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. *Id.* To be covered, a Part D drug must be used for a "medically accepted indication," as defined in section 1927(k)(6) of the Act. Section 1860D-2(e)(1) of the Act. Section 1927(k)(6) of the Act defines a "medically accepted indication" as "any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i)." *Id.* Section 1927(g)(1)(B)(i) lists the approved compendia as *American Hospital Formulary Service Drug Information* (AHFS-DI), *United States Pharmacopeia-Drug Information* (or its successor publications) (USPDI), or the *DRUGDEX Information System* (DRUGDEX).

Section 182 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275, enacted July 15, 2008) revised the definition of a Part D drug found in section 1860D-2(e)(1) of the Act. The change was effective January 1, 2009. The Centers for Medicare and Medicaid Services (CMS) published an interim final rule, effective January 16, 2009, which revised the definition of a Part D drug, and,

specifically, the definition of "medically accepted indication" in 42 C.F.R. § 423.100. 74 Fed. Reg. 2881 (Jan. 16, 2009).

As pertinent herein, in order to be covered under Part D under the above statute and implementing regulations, a drug must be approved by the FDA as described in section 1927(k)(2)(A)(i), which means that it is a drug marketed pursuant to a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA); or the drug must be exempt from FDA approval under section 1927(k)(2)(A)(ii) of the Act.

The Federal Food, Drug and Cosmetic Act of 1938 (FD&C Act, 21 U.S.C. section 351) and the Drug Amendments of 1962 (Pub. L. 87-781) require that a new drug be safe and effective to obtain FDA approval for marketing. The 1962 Drug Amendments established a "grandfather clause" exempting from the effectiveness requirement those drugs whose composition and labeling have not changed since the date the amendments were enacted and, if, prior to enactment, the drug was used or commercially sold within the United States, was not a "new drug" as defined in the FD&C Act at that time, and was not covered by a new application. *Id.* Section 1927(k)(2)(A)(ii) of the Act enables Medicare coverage for grandfathered drugs. Courts have "very narrowly construed the 'grandfather clauses' in the FD&C Act." *See generally United States v. An Article of Drug (Bentex Ulcerine)*, 469 F.2d 875, 878 (5th Cir. 1972); *United States v. Articles of Drug Consisting of the Following: 5,906 Boxes*, 745 F.2d 105, 113 (1st Cir. 1984).

The regulations at 42 C.F.R. § 423.578 implement the Part D formulary exceptions process. However, limitations to the exceptions process are found at 42 C.F.R. § 423.578(e), which provides that "[n]othing 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

In spite of the Plan's apparent interim coverage of the Opium Tincture on March 20, 2014, the issue now before the Council is the propriety of a coverage exception for this drug under section 1927(k)(2)(A)(ii) of the Act. As the appellant recognizes, this is not the first time the Council has reviewed Medicare Part D coverage of Opium Tincture. While the Council conducts *de novo* review of each case before it, meaning that it

is not necessarily bound by any prior decision on an issue, the facts established in certain cases, such as whether a drug is considered "grandfathered" under the Act, may remain relevant to the extent that a similar case has been correctly decided under applicable legal standards. The analysis which follows relies extensively on the research applied in the Council's earlier considerations of coverage for Opium Tincture, as there is no argument or evidence that these predicate facts have changed. *See, e.g.,* Council Dockets M-14-657, M-11-363.

In 2009, the Council was asked by CMS to review a case, on the Council's own motion, in which an ALJ found coverage of the Opium Tincture under the "grandfathered drug" exception in the Part D law.[1] There, CMS asserted that Opium Tincture was not a covered drug because it was not FDA-approved and was not subject to the "grandfathered drug" exception of section 1927(k)(2)(A)(ii) of the Act. CMS further argued that FDA Compliance Policy Guidance Manual, section 440.100, entitled "Marketed New Drugs Without Approved NDAs" (CPG 7132c.02), referenced the "grandfathered drug" clause and stated that "the FDA believes there are very few drugs on the market entitled to grandfather status."

In declining to review that case, the Council agreed that Opium Tincture was not an FDA-approved drug. However, the Council determined that the question of whether the ALJ's decision should be reviewed turned on whether Opium Tincture was subject to the grandfathered drug exception in section 1927(k)(2)(A)(ii) of the Act.

After extensive research, the Council determined that the drug was, in fact, subject to such an exception and thus met the definition of a covered Part D drug. The Council consulted the United States Pharmacopoeia Drug Index (USPDI), Volume III, "Approved Drug Products and Legal Requirements," Part 1, Section III, which contains a "Listing of 'Pre-1938' Products." The USPDI is one of a few limited compendia recognized by section 1927(g)(1)(B)(i) of the Act as an authoritative source for determining the coverage status of prescription drugs and reflects the level of confidence Medicare places on this resource. The introduction to Part 1, Section III states as follows:

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[1] *See,* the Council's October 8, 2009, Order in the case of V.B.M., available at http://www.hhs.gov/dab/divisions/medicareoperations/macdecisions/vbm.pdf

> The Federal Food, Drug and Cosmetic Act of 1938 required that drugs be shown to meet certain safety requirements prior to their being marketed. Drugs that were already being marketed at that time were "grandfathered" and were allowed to remain on the market without further regulatory approval if they were labeled with the same conditions of use. Many of these products remain on the market today. Because these products technically have never been *approved* by FDA, they do not appear in the listing of approved drug products with therapeutic equivalence evaluations (the "Orange Book").
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> The following listing identifies drug products that we believe are considered "pre-1938" or "grandfathered" and are still currently available. The list was developed by comparing an earlier general listing of frequently prescribed "pre-1938" drug entities developed by the U.S. Food and Drug Administration against current dosage form listings in the "Orange Book." The listing is not necessarily complete and comments are welcomed. Additions to or deletions from this list will be shown in future issues of *Update.* The listing of these products should not be interpreted as an attestation by USP as to their actual availability or the general recognition of safety and efficacy of the articles for medical or legal purposes or that a final determination has been made by the FDA.

"Opium Tincture" appeared on this list, along with a list of perhaps 100 other pre-1938 "grandfathered" drugs. This weighed heavily against the FDA's assertion, in its Compliance Policy Guidance Manual, that there are few if any of these drugs remaining on the market, especially where this brief remark made no reference to the specific drug at issue. Moreover, other than in the USPDI, we found no other authoritative guidelines on pre-1938 grandfathered drugs or on the legal status of Opium Tincture by prescription.

The Council also searched for "Opium Tincture" on the FDA's website. This search produced very few references to the drug and none addressing its "grandfathered" status (or lack of such status) when sold by prescription, rather than over-the-counter. While the Council agreed that the FDA should be making decisions on the grandfathered status of marketed drugs rather than an

ALJ, the FDA apparently has not addressed the status of this U.S.-marketed prescription drug either for purposes of approving its usage or requiring its manufacturer to file a new drug application. Nonetheless, there is some indication that the FDA had been involved in the labeling of Opium Tincture, as the FDA requires it to bear a warning label stating "POISON" due to its potency and potential for overdose. Moreover, in May 2004, the FDA issued a warning notifying the public that "Opium Tincture" was not to be confused with "Camphorated Opium Tincture" (Paregoric), as Opium Tincture has 25 times the potency of Paregoric.[2] These actions suggest that the FDA is involved in the labeling and monitoring of Opium Tincture.

As the ALJ appears to have recognized, neither the ALJ nor the Council are experts in Food and Drug law or in the assessment of drug safety or efficacy. However, the Council notes that Congress cross-referenced section 1927(k)(2) in defining "covered part D drug[s]" in section 1860D-2(e) of the Act. That section specifically includes the reference to drugs commercially sold or marketed prior to the Drug Amendments of 1962; thus, it is unlikely that Congress considered such drugs to be non-existent. In any event, the USPDI listed Opium Tincture as a pre-1938 grandfathered drug, based on extensive research.

For these reasons, the Council finds that Opium Tincture meets the definition of a Medicare-covered Part D drug under the grandfathered drug provisions of section 1927(k)(2)(A)(ii). Moreover, the appellant, both directly and through documentation submitted by her physician, has convincingly argued that all other drugs in the same pharmaceutical category which have been used to treat her condition have been proven ineffective and that she has a clear medical need for the specific drug requested. *See, e.g.,* Exh. 2 at 17, 19, 20, 22, 23, 25, 29, 30, and 31. Thus, the appellant meets the criteria for a formulary exception for the drug under the provisions of 42 C.F.R. § 423.578(b).

DECISION

It is the decision of the Medicare Appeals Council that the appellant's prescription for Opium Tincture meets the definition of a Medicare-covered Part D drug under the grandfathered drug provisions of section 1927(k)(2)(A)(ii) of the Act. The plan must provide or reimburse the appellant for opium tincture, 10

[2] *See* www.fda.gov/downloads/Drugs/DrugSafety/MedicationErrors/UCM080654

mg., retroactive to the final date of the plan's initial authorization, on June 12, 2014. Nothing in this decision should be construed to require the plan to waive the usual cost-sharing for the prescribed drug, which the appellant otherwise would be required to pay.

The ALJ's decision is reversed.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson
Administrative Appeals Judge

/s/ Constance B. Tobias, Chair
Departmental Appeals Board

Date: April 9, 2015