

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DEPARTMENTAL APPEALS BOARD

ORDER OF MEDICARE APPEALS COUNCIL

**In the case of**

V.B.M.  
\_\_\_\_\_  
(Appellant)

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\_\_\_\_\_  
(Beneficiary)

Anthem Blue Cross & Blue  
Shield  
\_\_\_\_\_

(Prescription Drug Plan)

**Claim for**

Prescription Drug Benefits  
(Part D)  
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\_\_\_\_\_  
(HIC Number)

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(ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated May 20, 2009. The Medicare Appeals Council (Council) received a referral from MAXIMUS Federal Services, the Part D Independent Review Entity (MAXIMUS) acting on behalf of the Centers for Medicare & Medicaid Services (CMS), asking the Council to review the ALJ's decision. The Council has decided not to review or reverse the ALJ's decision, as requested by MAXIMUS.

In his decision, the ALJ found that the beneficiary should receive a formulary exception and Part D coverage for Opium Tincture, a non-FDA approved drug used to treat the beneficiary's severe diarrhea and malabsorption relating to Crohn's disease. The record contains a letter from the beneficiary's treating physician of twenty years, documenting the fact that the beneficiary has used this drug successfully for the past ten years and that it is the only treatment which has been successful for her life-threatening condition. The beneficiary has credibly asserted that she is able to work and lead a relatively normal life and that, without this drug, she would be bed bound and spending long periods of time in the hospital with uncontrollable weight loss and diarrhea. For these reasons, the Council will not reverse the ALJ's decision without a compelling reason to do so.

The ALJ based his decision on a finding that Opium Tincture has been marketed since well before the Drug Amendments of 1962.

Thus, the ALJ found, it was a "grandfathered" drug within the exception of section 1927(k)(2)(A)(ii) of the Social Security Act and is thus eligible for coverage under Part D of Medicare. In response, MAXIMUS Federal Services has argued that Opium Tincture does not qualify for such exception and that the ALJ did not have the authority to make such finding. With its agency referral memorandum, MAXIMUS introduced a copy of FDA Compliance Policy Guidance Manual, section 440.100, entitled "Marketed New Drugs Without Approved NDAs [New Drug Applications] (CPG 7132c.02)," which notes the grandfather clauses in the Act and states that "the FDA believes there are very few drugs on the market entitled to grandfather status."

However, despite this broad assertion, the Council has 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 title XVIII (Medicare) as an authoritative source for determining the coverage status of chemotherapy drugs, and reflects the level of confidence Medicare places on this resource. The introduction to Part 1, Section III states as follows:

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").

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" appears on this list, along with a list of perhaps 100 other pre-1938 "grandfathered" drugs. This weighs heavily against the FDA's assertion in its drug compliance policy that there are few if any of these drugs remaining, particularly when such brief remark makes no reference to the drug at issue. Moreover, other than in the USPDI, we have found no other authoritative guidelines on pre-1938 grandfathered drugs or on the legal status of Opium Tincture by prescription.

In fact, a search of "Opium Tincture" on the FDA's website produced very few references to the drug and none addressing its "grandfathered" status (or lack of such status) when sold by prescription (as opposed to over-the-counter). While the Council agrees 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 Opium Tincture 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.<sup>1</sup> These actions suggest that the FDA is involved in the labeling and monitoring of Opium Tincture.

Finally, the Council has determined that "Opium Tincture" is on the formularies of many large Medicare Part D drug plans elsewhere in the country. For example Opium Tincture is on the 2008 Medicare Part D formulary of Health Insurance Plan of New York for use as a gastrointestinal drug. It is on the 2007 Medicare Part D PDP formulary for Kaiser Permanente Medicare Plus as a brand name or generic analgesic/antipyretic, and appears as such on the Part D formulary for Blue Medicare Rx,

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<sup>1</sup> See, generally,

[www.fda.gov/downloads/Drugs/DrugSafety/MedicationErrors/UCM080654](http://www.fda.gov/downloads/Drugs/DrugSafety/MedicationErrors/UCM080654);  
<http://en.wikipedia.org/wiki/Laudanum>.

Value & Plus Plans. It is listed on the formulary for Pacificare's Secure Horizons Retiree Plan, a Medicare Part C and D plan, where it is listed as a Tier 1 bowel treatment drug.<sup>2</sup> Each of these plans covers Opium Tincture as a formulary drug where it is medically reasonable and necessary and other coverage requirements have been met.

While neither the ALJ nor the Council are experts in Food and Drug law or in the assessment of drugs, MAXIMUS has not provided the Council with a sufficient basis to reverse the ALJ's finding that Opium Tincture fits within the exception of section 1927(k)(2)(A)(ii). The Council notes that the Medicare Part D prescription drug program is less than four years old, and 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 lists Opium Tincture as a pre-1938 grandfathered drug based on research. Moreover, several major Medicare Part D prescription drug plan formularies include Opium Tincture as a covered formulary drug, despite its non-FDA approved status, presumably on the grounds that it is available by prescription, legally sold in the United States as a grandfathered drug, and is medically reasonable and necessary for some uses. Given the both limited and compelling medical circumstances presented in this case, the Council finds that the ALJ did not err in finding Opium Tincture to be within the definition of a Part D drug and that the beneficiary is entitled to a formulary exception given her medical circumstances.

Accordingly, the ALJ's decision is binding. The Council refers the case to Maximus for effectuation of the ALJ's decision.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson  
Administrative Appeals Judge

Date: October 8, 2009

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<sup>2</sup> See, e.g. [www.hipusa.com/downloads/medicare/2008/formulary/HIP\\_drug\\_formulary/partD](http://www.hipusa.com/downloads/medicare/2008/formulary/HIP_drug_formulary/partD); [https://brokernet.kp.org/broker/wcm/connect/fo175604ee2d4829a329bc3110b4125/oh\\_medicare\\_formulary\\_07](https://brokernet.kp.org/broker/wcm/connect/fo175604ee2d4829a329bc3110b4125/oh_medicare_formulary_07).