

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL  
Docket Number: M-15-1067

In the case of

Claim for

Estate of E.B.  
(Appellant)

Hospital Insurance Benefits  
(Part A)

Emily Back (dec'd)  
(Beneficiary)

XXX-XX-0566A  
(HIC Number)

Noridian Healthcare  
Solutions, Inc.  
(Contractor)

1-2655007265  
(ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated March 31, 2015, which concerned the appellant-estate's claim for Medicare coverage of Actiq/fentanyl "lollipops" purchased for the beneficiary on February 2, 14, and 23, 2008. The ALJ determined that the drug was not covered under Medicare Part B because the drug was self-administered and because the beneficiary, by electing hospice services, had waived any right to Part B payment for services related to the management of her terminal illness. The ALJ also held that payment could not be made to the appellant under section 1879 of the Social Security Act (Act). The appellant, through the beneficiary's husband, 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). We admit the appellant's timely filed request for Council review into the record as Exhibit (Exh.) MAC-1. For the reasons we explain below, we reverse the ALJ's decision and find that Medicare Part A coverage is available under the hospice benefit for the drug furnished to the beneficiary on the dates of service at issue.

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**BACKGROUND**

The record reflects that, on October 16, 2007, the beneficiary signed an "informed consent and hospice benefit election form." Exh. 2 at 3. The form notified the beneficiary that, by electing hospice care, she waived all rights to Medicare payments for services related to her terminal illness, except for the services furnished by the attending physician and the hospice provider. *Id.*

Due to increased pain, on February 2, 2008, the beneficiary's attending physician prescribed Actiq transmucosal lollipops, every six hours as needed for pain. Exh. 2 at 5. The physician consulted with the interdisciplinary work group and the plan of care was revised to include the new drug. *Id.*; *id.* at 34. The physician subsequently explained that the beneficiary "had been on ever increasing doses of oxycodone, then fentanyl patch . . . plus oral morphine . . . none of which effectively relieved her pain." *Id.* at 1. Therefore, he wrote, he prescribed oral fentanyl, "which DID afford her some relief." *Id.* Further, according to the physician, the hospice would not provide the drug "due to cost." *Id.* The beneficiary's husband explained that the hospice refused to provide or pay for the drug, so he filled the prescription at a pharmacy and paid directly. Exh. 1 at 15; Exh. 2 at 2.

The beneficiary's husband then sought reimbursement from the hospice provider, which refused to reimburse him. *Back v. Sebelius*, 684 F.3d 929, 930 (9th Cir. 2012). The hospice provider informed the beneficiary's husband that he should file a claim with the Home Health and Hospice contractor with geographical jurisdiction. *Id.* His claim never proceeded, though, because the Centers for Medicare & Medicaid Services (CMS) ultimately informed him that the provider must submit a claim. *Id.* at 931. He then filed suit against the Secretary of the Department of Health and Human Services (Secretary) in federal district court alleging that there was not an administrative procedure to appeal the hospice provider's refusal to furnish a needed drug. *Id.* The district court dismissed the suit based on exhaustion grounds, as the court found that the beneficiary's husband had not exhausted his administrative remedies. *Id.*

The beneficiary's husband appealed and the United States Court of Appeals for the Ninth Circuit determined that his appeal was moot because, pursuant to the Secretary's judicial admission,



the administrative appeals procedures found at subpart I of 42 C.F.R. section 405 were available to a beneficiary seeking to appeal a hospice provider's denial of care. 684 F.3d at 932-33. Therefore, because the remedy that he sought was already available, the case was moot. *Id.* at 933. In its opinion, the Ninth Circuit noted that the Secretary had admitted that the beneficiary's husband had been given incorrect information with respect to the contractor with whom he should file his claim. *Id.* at 931 n.1. The Secretary stated that the beneficiary's husband could have filed a claim with the Part A/Part B contractor servicing residents of the beneficiary's state. *Id.* The Court also noted that the Secretary had agreed to waive the timely filing requirement in this case so the beneficiary's husband could appeal the hospice's denial of services. *Id.* at 933 n.5.

The beneficiary's husband then submitted a claim for coverage with the Part A/Part B contractor<sup>1</sup> with geographical jurisdiction. Exh. 1 at 22. The contractor denied the claim initially and on redetermination stating that "Medicare does not pay for these services" and held the estate liable for the non-covered charges. *Id.* at 17-18. He then submitted a request for reconsideration to the Part B Qualified Independent Contractor (QIC), explaining that his wife had fallen in August 2007, sustaining severe injuries, and began hospice care in October 2007. *Id.* at 14-16. He further explained that he sought reimbursement for the prescriptions that he filled, the drug was medically necessary, and the hospice provider should have provided it. *Id.* at 15. He stated that, "[t]o date, I have not received a valid determination from Medicare as to whether the medication I purchased for my wife is entitled to coverage and reimbursement under the Medicare Part A hospice benefit." *Id.* With his request, he submitted medical records from the hospice provider along with the plan of care/verbal order, which added the fentanyl lozenges. *Id.*

The QIC denied coverage after considering only whether the drug was covered under the Part B benefit for drugs that are incident to a physician's service. Exh. 1 at 6. The QIC ultimately

<sup>1</sup> We note that the contractor identified in the Ninth Circuit's decision seems different from the contractor with which the beneficiary's husband filed his claim, presumably because CMS awarded the contract to a different company between the time the Court dismissed the lawsuit and when the appellant filed his claim. See *Back*, 684 F.3d at 931 n.1; <https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Jurisdiction-E-Implementation-Schedule.html> (last visited Sept. 18, 2015).

denied the claim because "there was no indication in the record of when the patient actually received or took the fentanyl lollipops" and because "the drug must be of a form that is not usually self-administered." *Id.* at 7. The QIC held that the beneficiary was responsible for the non-covered charges because self-administered drugs are excluded from coverage under Part B. *Id.* The QIC did not address the argument that the drug should be covered under the Part A hospice benefit.

The beneficiary's husband then requested ALJ review and waived his right to a hearing, asking the ALJ to render a decision on the record presented. Exh. 1 at 1-3; Exh. 4 at 1-4. He asserted that the QIC's decision, like the redetermination before that, "failed to validly determine whether the medication I purchased for my wife is entitled to coverage and reimbursement under her Medicare Part A hospice benefit." Exh. 1 at 2. He further asserted that "[t]his violates my appeal rights under Medicare law, as well as my right to due process under the federal constitution." *Id.*

In the decision, the ALJ noted that Medicare will pay for services and supplies incident to the service of a physician, which includes drugs that are not usually self-administered. Dec. at 3. He also noted that a beneficiary who elects hospice waives all right to Medicare Part B payments for services related to the terminal illness, except for the professional services of the attending physician. *Id.* The ALJ then denied Part B coverage because the fentanyl oral lozenges were self-administered and because the drug was related to the management of the beneficiary's terminal illness, so the beneficiary had waived her right to Part B payment. *Id.* The ALJ determined that the denial was "technical" so the limitation on liability provision of section 1879 would not apply. *Id.* at 3-4. Therefore, the ALJ determined that payment could not be made to the appellant pursuant to section 1879. *Id.* at 4. The ALJ did not address whether the medication was covered under Part A or whether the hospice should have furnished it for the beneficiary.

The beneficiary's husband then timely requested Council review. See Exh. MAC-1. He asserts, as he did before the QIC and the ALJ, that the medication was "medically necessary and should have been provided by hospice and covered by Medicare." *Id.* He contends that the ALJ erred in failing to determine whether the drug was covered under Medicare Part A's hospice benefit and that "[t]his violates my appeal rights under Medicare law, as

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well as my right to due process under the federal constitution." *Id.*

### DISCUSSION

We have reviewed the record in this case as well as the request for review and ultimately find that Medicare will cover the drug at issue under the Part A hospice benefit. In the Ninth Circuit decision, the court stated that the Secretary indicated that the beneficiary's husband could file his claim with the Part A/Part B contractor and that the appeals procedures under subpart I of 42 C.F.R. section 405 were available to him to appeal the hospice's denial of care. However, when the Medicare contractor reviewed the claim after the Ninth Circuit's decision, the contractor only stated generally that Medicare did not cover the drug and did not specifically address whether the drug should be covered under the hospice benefit. Likewise, the QIC and the ALJ did not address this issue. The claim at issue is essentially an appeal of the hospice provider's denial of services. The beneficiary's husband filed the claim as directed by the court and through the Secretary's indication, yet none of the prior adjudicators analyzed this specific issue. Considering the issue before us, whether the hospice benefit covers the drug the hospice provider refused to furnish to the beneficiary, we find that, in this case, Medicare will cover the drug at issue.

When a beneficiary elects hospice benefits, she waives her right to Medicare payment for services (other than those provided by the hospice or physician's services furnished by the attending physician) that are "related to the treatment of the individual's condition with respect to which a diagnosis of terminal illness has been made." Act, § 1812(d)(2)(A)(ii)(I). See also 42 C.F.R. § 418.24(d). The Act defines "hospice care" to include "medical supplies (including drugs and biologicals) and the use of medical appliances, while under [a plan of care]." § 1861(dd)(1).

The implementing regulations in effect on the dates of service at issue state that "hospice services must be reasonable and necessary for the palliation or management of the terminal illness as well as related conditions." 42 C.F.R. § 418.200. In addition, the beneficiary must properly elect the hospice benefit, a plan of care must be established, and the services must be furnished pursuant to the plan of care. *Id.* Finally, a

physician must certify that the beneficiary is terminally ill. *Id.*

Covered services include "Medical appliances and supplies, including drugs . . . as defined in section 1861(t) of the Act and which are used primarily for the relief of pain and symptom control related to the individual's terminal illness." 42 C.F.R. § 418.202. Covered medical supplies are those that are included in the written plan of care. *Id.* See also Medicare Benefit Policy Manual (MBPM), CMS Pub. 100-02, Ch. 9, § 40.1.6. (Rev. 10-2003). Drugs defined in section 1861(t) of the Act are those that are found, as relevant here, in certain listed formularies, including the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs of Accepted Dental Remedies. See Act, § 1861(t).

In this case, the beneficiary's husband is pursuing coverage under Medicare's hospice benefit of the Actiq lollipops he paid out-of-pocket for his wife. The beneficiary signed an "Informed Consent and Hospice Benefit Election Form," which explained that the beneficiary waived Medicare payments for services related to her terminal illness, except those provided by the attending physician and the hospice provider. Exh. 2 at 3. The form further stated that the beneficiary would be "responsible for the cost of care for [her] terminal illness" if she sought care other than what was considered "medically necessary by the hospice interdisciplinary team and documented on [her] plan of care." *Id.* Therefore, it is clear that the beneficiary elected the hospice benefit and, therefore, was eligible for hospice care.

Having reviewed the record, it is apparent that the Actiq/fentanyl lollipops at issue met the definition of "medical supplies" that are covered under the hospice benefit. The drug was ordered by the attending physician to manage the beneficiary's increasing pain. See Exh. 2 at 5, 29-32. In addition, the beneficiary subsequently received fentanyl intravenously while in a skilled nursing facility under hospice care. *Id.* at 5. Therefore, the record makes clear that the drug was reasonable and necessary for the palliation of the beneficiary's terminal illness. Further, the drug was covered under the beneficiary's plan of care. *Id.*, *id.* at 33-34. In this way, we are convinced that the fentanyl lollipops meet the definition of "drug" specified in section 1861 of the Act.

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Finally, the record contains a certification of terminal illness. Exh. 2 at 25.

For these reasons and for the unique set of circumstances presented in this case, we conclude that Medicare will cover the fentanyl lollipops for dates of service of February 2, 14, and 23, 2008.

**DECISION**

It is the decision of the Medicare Appeals Council that Medicare will cover the Actiq/fentanyl "lollipops" purchased by the beneficiary's husband on February 2, 14, and 23, 2008. The contractor is directed to process this claim accordingly. The ALJ's decision is reversed.

MEDICARE APPEALS COUNCIL



Deborah S. Samerow  
Administrative Appeals Judge



Stanley I. Osborne, Jr.  
Administrative Appeals Judge

Date: OCT 14