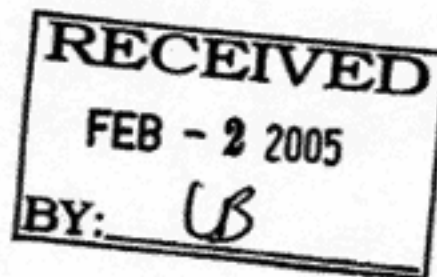


DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
2520 Lord Baltimore Drive, Suite L, Mail Stop LB-01-22
Baltimore, Maryland 21244-2670



Medicare/Medicaid Hearings Group

JAN 31 2005



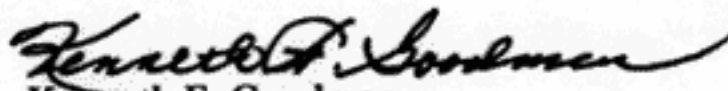
George F. Indest
The Health Law Firm
220 East Central Parkway, Suite 2030
Altamonte Springs, Fl. 32701

Re: Orthotics for Life, Inc..
Medicare Supplier No. 4396540001

Dear Mr. Indest:

Enclosed please find my decision concerning the above captioned case. Please contact me at 410-786-0967 if you have any questions concerning the decision.

Yours truly,


Kenneth F. Goodman
CMS Review Official

cc:

Elisabeth Horn
Provider Integrity Group – Appeals
Division of Provider/Supplier Enrollment
C3-02-16
7500 Security Boulevard
Baltimore, Md. 21244-1850

Alberto T. Bustillo
Medicare Hearing Officer
11447 S.W. 86th Lane
Miami, Florida 33173-4219

Medicare National Supplier Clearinghouse
Hearings and Appeals Department
P.O. Box 100142
Columbia, S.C. 29202-3142

Appeal Decision by the Centers for Medicare and Medicaid Services

In the case of:

Orthotics for Life, Inc.

Appeal from Reinstatement of
Medicare Supplier Billing Number
Carrier Hearing Officer's Decision
dated October 19, 2004

v.

Palmetto GBA and
National Supplier Clearing House

CMS Appeals Docket No. S-05-011

Jurisdiction

This appeal is provided pursuant to 42 C.F.R. §405.874(d). The CMS official designated by the Administrator of CMS for this purpose is the undersigned, Kenneth F. Goodman.

Background

On September 3, 2004, the National Supplier Clearinghouse ("NSC") revoked the durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS") Medicare Supplier Number that was issued to Orthotics for Life, Inc. ("Orthotics"). The suspension followed an NSC inspection of Orthotics business operations that indicated that Orthotics was not in compliance with standards 1, 2, 4, 9, 12, 17, and 18 of 42 C.F.R. §424.57. Subsequent to the revocation, Orthotics supplied additional information that resolved the issues related to standards 17 and 18. However, the NSC determined that Orthotics remained in continued noncompliance with standards 1, 2, 4, 9, and 12. On September 29, 2004, Orthotics filed a timely appeal of the NSC denial decision. The Carrier Hearing Officer conducted a telephone hearing on October 19, 2004. At the hearing, the Carrier Hearing Officer reviewed the NSC's History Summary in which the NSC maintained that its revocation of Orthotics' number was proper and that Orthotics remained in noncompliance with standards 1, 4, 9, and 12. On October 19, 2004, the Carrier Hearing Officer issued a written decision in which he rejected the NSC's position and concluded that Orthotics was in compliance with each of the four supplier standards raised by the NSC's summary.

NSC subsequently advised Orthotics that it intended to seek administrative review of the decision and filed its formal petition with CMS on October 26, 2004. Orthotics's petition asserted that Orthotics remained in non-compliance with standards 1 and 4 because no owner or employee of Orthotics was a licensed orthotist. NSC now seeks CMS's review of those issues.

Issue

Was the decision of the Carrier Hearing Officer to reverse the revocation of Orthotics' Medicare Supplier Number supported by substantial evidence and, accordingly, should the decision be affirmed or reversed?

Discussion

This reviewing official thoroughly examined the entire record furnished by the Carrier Hearing Officer. I find that the Carrier Hearing Officer's decision reversing the NSC's suspension of Orthotics' Medicare Supplier Number was supported by substantial evidence at the time it was issued. The Carrier Hearing Officer decision is affirmed.

Findings

To qualify for a DMEPOS supplier number, a supplier must meet certain standards. Those standards are set forth at 42 C.F.R. §424.57(c)(1) through (21). As discussed above, the NSC revoked Orthotics' Medicare supplier number. Orthotics appealed the revocation to the Carrier Hearing Officer. The Carrier Hearing Officer reversed the NSC's revocation and the NSC files for CMS review.

In its October 26, 2004, petition to this office, NSC provided its reasons for concluding that Orthotics does not meet supplier standards 1 and 4. At the hearing, the supplier presented evidence that it employed licensed orthotists and podiatrists to provide orthotic services. The NSC, in turn, examined the materials supplied to the Carrier Hearing Officer but found the evidence unpersuasive that any owner or employee of Orthotics was a licensed orthotist. Based upon these conditions, NSC restated the rationale that it offered in its initial revocation notice dated September 3, 2004.

Standard 1 requires that a supplier "operates its business and furnishes Medicare-covered items in compliance with all applicable Federal and State licensure and regulatory requirements." The NSC contends that Orthotics is not in compliance with this standard because no owner or W-2 employee is licensed in orthotics and or prosthetics. NSC reasons that because Medicare reimbursement for orthotic and prosthetic devices includes reimbursement for services as well as equipment, evaluation of the patient, measurement and /or casting and fitting must be done by an individual licensed in orthotics or prosthetics. The NSC further contends that, since Orthotics did not employ such an individual, it is not licensed to provide those services and is, therefore, in violation of standard 1.

Standard 4 states in a part that the supplier "fills orders, fabricates, or fits items from its own inventory or by contracting with other companies for the purchase of items necessary to fill the order." The NSC contends that, absent appropriately licensed staff, Orthotics cannot supply the fitting/fabrication services required under standard 4. The NSC contends that Orthotics is, therefore, in violation of standard 4.

My examination of the Carrier Hearing Officer's file indicated that Orthotics claimed that it had appropriate licensed staff available to supply orthotic services. In support of that claim, Orthotics supplied copies of Florida state podiatric physician licenses for Bruce Kramer and Arthur Aronson, Ohio state podiatric physician licenses for Robert Jankas and a Florida orthotic fitter license for Jonathan Fogg. In addition Orthotics provided an employee Withholding Allowance Certificate (IRS Form W-4) and copies of pay stubs for each.

The pivotal issue in determining whether Orthotics satisfies the requirements of standards 1 and 4, is Orthotics' actual relationship with the individuals that it identified as employees. Consideration of that relationship requires this reviewing official to revisit the current CMS policy on contracting for services in the supply/delivery of durable medical equipment.

Section 1834 of the Social Security Act contains the provisions for the payment of Medicare funds for durable medical equipment. CMS policy holds that Section 1834 prohibits contracting for orthotic and prosthetic services. In the past, this office performed an analysis of that section to determine if the crafters of the regulation intended to allow suppliers to enter into contracts for comprehensive orthotic and prosthetic services. The analysis included an examination of the language of the standards as well as the language of the October 11, 2000, preamble. The only standards that allow a supplier to enter into a contract with another entity are standards 4 and 14. Standard 4 states in part that the supplier "fills orders, fabricates, or fits items from its own inventory or by contracting with other companies for the purchase of items necessary to fill the order (emphasis added). 42 C.F.R. §424.57(c)(4). Standard 14, which also contains language concerning a supplier entering into a contract, states that the supplier "must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries." 42 C.F.R. § 424.57(c)(14). A plain reading of the regulatory language indicates that nothing more than supply delivery or repair is to be contracted out by a Medicare supplier. That conclusion is further supported by a review of the preamble language. The comments concerning the contract provisions of supplier standard 4 clearly contemplate only supply delivery. "We have clarified this standard to require only copies of contracts that a supplier has with other entities that deliver supplies to Medicare beneficiaries on the supplier's behalf or that provide supplies to the supplier for use in providing items to Medicare beneficiaries. This would include componentry." 65 Fed. Reg. 60377 (Oct. 11, 2000).¹ The language of the preamble supports the conclusion that nothing more than supply delivery or repair was to be contracted out by a Medicare supplier. Based upon this analysis, this reviewing official considers CMS's Section 1834 policy consistent with the intent and language of the regulation and I will continue to enforce its prohibitions.

Given those prohibitions, Orthotics must demonstrate that it has a licensed professional on its staff to provide orthotic and prosthetics services. Orthotics contends that Messrs. Kramer, Aronson, Jankas and Fogg are licensed professionals who are currently employees of their business and offered professional licenses, pay stubs and W-4's in support of their employee status. A W-4 is a request for tax withholding from an individual's pay and, by itself, does not evidence an employment agreement or conclusively establish an employer/employee relationship. In this case, however, the W-4's are accompanied by actual pay stubs that provided the amounts of compensation and tax/FICA withholding afforded each individual in the course of their affiliation with Orthotics. The tax withholding information is persuasive on the issue of the Orthotics role as an employer and confirms the status of Messrs. Kramer, Aronson, Jankas and Fogg as Orthotics' employees. Absent a challenge from the NSC relative to the validity of the pay stubs or the professional licenses, I must conclude that Orthotics has licensed professionals who are

¹ The preamble contained no discussion covering the standard 14 language for equipment repairs. See 65 Fed.Reg. 60377.


currently employees of their business to provide orthotics services. Accordingly, I find Orthotics in compliance with standards 1 and 4.

To meet the requirements to furnish orthotic and prosthetic equipment, and the attendant services necessary to supply such equipment, Orthotics must employ licensed professionals to supply orthotic services. The record, and the supplemental information offered in its support, indicates that Orthotics employs licensed podiatrists and orthotists to provide those services. Consequently, this reviewing official concludes that Orthotics is in compliance with supplier standards 1 and 4. Orthotics may have its Medicare supplier number reinstated with its attendant privileges.

Decision

The Carrier Hearing Officer's decision is **affirmed**.

January 28, 2005
Date


Kenneth F. Goodman
CMS Review Official

THIS CONSTITUTES THE FINAL ADMINISTRATIVE DECISION OF THE CENTERS FOR MEDICARE AND MEDICAID SERVICES. NO FURTHER ADMINISTRATIVE APPEALS ARE AVAILABLE.