

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:)	
)	
Medical Resources Associates, LLC,)	
)	Date: March 20, 2008
Petitioner,)	
)	Docket No. C-05-600
- v. -)	Decision No. CR175 ^o
)	
Centers for Medicare &)	
Medicaid Services.)	

DECISION

I affirm the determination of the Medicare Part B Hearing Officer (Hearing Officer) to uphold the denial by the Medicare Part B Carrier, HGS Administrators (the Carrier), of Medical Resources Associates, LLC (Petitioner) application for enrollment as a Medicare provider. I find that the Hearing Officer correctly determined that Petitioner does not meet the regulatory requirements for obtaining a Medicare Provider Identification Number (PIN or enrollment number).

I. APPLICABLE AUTHORITY

Title XVIII of the Social Security Act (Act) established the Medicare program, a federally funded health insurance program that provides payment for covered services furnished to aged and certain disabled individuals. Act, Section 1801-1896. Section 1831 of the Act establishes the supplementary medical insurance benefits program for the aged and disabled known as Medicare Part B.

Section 1866(j) of the Act, as amended by section 936 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, authorized the Secretary of Health and Human Services to establish a process for the enrollment in the Medicare program of providers of services and suppliers. Section 1866(j)(2) of the Act gives providers and suppliers appeal rights, for certain determinations involving enrollment, using the procedures that apply under section 1866(h)(1)(A) of the Act.

Those procedures are set out at 42 C.F.R. Part 498, *et seq.*, and provide for hearings by Administrative Law Judges and review by the Departmental Appeals Board (Board).

Pursuant to 42 C.F.R. § 410.33(a), an Independent Diagnostic Testing Facility (IDTF) is described as “a fixed location, a mobile entity, or an individual nonphysician practitioner . . . [that is] independent of a physician’s office or hospital” where diagnostic procedures are carried out. “Carriers will pay for diagnostic procedures under the physician fee schedule only when performed by a physician, a group practice of physicians, an approved supplier of portable x-ray services, a nurse practitioner, or a clinical nurse specialist when he or she performs a test he or she is authorized by the State to perform.” 42 C.F.R. § 410.33(a)(1).

Pursuant to 42 C.F.R. § 410.33(a)(2), Medicare Part B will pay according to the physician fee schedule for diagnostic tests personally furnished by a qualified audiologist and these diagnostic tests are not required to be furnished in accordance with the criteria set forth in 42 C.F.R. § 410.33(b) through (e).

In provider appeals under 42 C.F.R. Part 498, the Board has determined that CMS must make a *prima facie* case that an entity has failed to comply substantially with federal requirements. *See MediSource Corporation*, DAB No. 2011 (2006). “*Prima facie*” means that the evidence is “[s]ufficient to establish a fact or raise a presumption unless disproved or rebutted.” *Black’s Law Dictionary* 1228 (8th ed. 2004); *see also Hillman Rehabilitation Center*, DAB No. 1611, at 8 (1997), *aff’d*, *Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (GEB) (D.N.J. May 13, 1999). To prevail, the entity must overcome CMS’s showing by a preponderance of the evidence. *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Center*, DAB No. 1665 (1998); *Hillman*, DAB No. 1611 (1997).

II. PROCEDURAL BACKGROUND

On July 26, 2004, the Carrier received Petitioner’s application for enrollment in the Medicare program as an Independent Diagnostic Testing Facility. CMS Exhibit (CMS Ex.) 12. By letter dated November 4, 2004, the Carrier notified Petitioner that its request to participate in the Medicare program was denied. CMS Ex. 6. By letter dated November 8, 2004, Petitioner notified the Carrier of its intent to appeal the Carrier’s decision. A Carrier Hearing Officer conducted an in-person hearing based on Petitioner’s appeal on March 8, 2005. On July 22, 2005, the Hearing Officer issued her unfavorable decision (Hearing Officer Decision) upholding the Carrier’s denial of Petitioner’s request to be enrolled in the Medicare program as an IDTF. CMS Ex. 1. By letter dated

September 15, 2005 (hearing request), Petitioner acting *pro se*, filed a timely appeal of the Hearing Officer Decision. The case was assigned to me for a hearing and decision. I held a telephone prehearing conference with the parties on January 4, 2006. Petitioner was represented at the prehearing conference by Ravinder Ahuja, President of Medical Resources Associates. I informed Mr. Ahuja that Petitioner had a right to retain an attorney to represent its interests in this legal matter. Mr. Ahuja indicated that he understood the right but he would represent the interests of Petitioner in this matter. After explaining my role as Administrative Law Judge and the hearing process, I informed the parties that this case could be addressed through an in-person hearing or through written submissions. The parties agreed that this case could be decided on written submissions. I set a schedule for the parties to file their submissions and directed that a copy of all submissions be served on the other party. *See Order*, dated January 31, 2006.

Petitioner filed its initial brief (P. Br.) along with nine exhibits (P. Exs.) 1-9. CMS filed its reply brief (CMS Br.) along with 17 exhibits (CMS Exs. 1-17). Petitioner filed a response brief (P. Response). Neither party has objected to the admissibility of any of the exhibits. I therefore admit into evidence P. Exs. 1-9, and CMS Exs. 1-17.

III. ISSUE

The issue in the matter before me is whether Petitioner qualifies as an Independent Diagnostic Testing Facility.

IV. FINDING OF FACT AND CONCLUSION OF LAW

I make a finding of fact and conclusion of law (Finding) to support my decision in this case. I discuss my finding in detail.

Petitioner has not established that it qualifies as an Independent Diagnostic Testing Facility

Petitioner applied for a Medicare Part B Provider Enrollment Number as a mobile Independent Diagnostic Testing Facility. Petitioner indicated that it intended to perform electronystagmography¹ (ENG) testing in physician's offices in two counties in the

¹ According to Medline Plus Encyclopedia, a website that is a service of the U.S. National Library of Medicine and the National Institutes of Health, electronystagmography is a test that evaluates the acoustic nerve, which aids with hearing and balance. *See* Medline Plus, Medical Encyclopedia at <http://www.nlm.nih.gov/medlineplus/ency/article/003448.htm>.

Commonwealth of Pennsylvania. P. Br. at 1; CMS Ex. 12, at 6. By letter dated November 4, 2004, the Carrier denied Petitioner's request to participate in the Medicare program because Petitioner did not meet CMS regulatory requirements for its supplier specialty as provided in 42 C.F.R. Part 410. CMS Ex. 6. In a letter dated November 18, 2004, the Carrier further explained its rationale for denial of Petitioner's application. In this letter, the Carrier explained that:

According to the Program Integrity Manual, Chapter 10, Section 5.2, Subsection 3.B, "Non-Physician Personnel (Technicians) Who Perform Tests," the carrier shall decide which organizations constitute a national credentialing body. Absent the state license for specific technicians, the carrier accepts certifications by credentialing bodies. The technicians employed by Medical Resources Associates did not have certification by a recognized credentialing body. The tests for which Medical Resources Associates requested approval, require performance by an audiologist or technician with appropriate certification under the supervision of a physician. According to the application, Medical Resources Associates does not employ an audiologist or technicians with appropriate certification and therefore does not meet Medicare requirements for the performance of these services.

CMS Ex. 4, at 1.

Petitioner argues that there is no national certification process for ENG technicians. Petitioner also maintains that manufacturers and distributors of ENG equipment have their own training programs that are administered by licensed audiologists. Petitioner contends that its technicians undergo the training administered by licensed audiologists. The physicians who supervise the technicians have accepted the training. Thus, Petitioner maintains, the ENG testing may be administered by the technicians under a supervising physician's general supervision. P. Br. at 2.

According to Petitioner, the American Academy of Audiology recognizes the training provided by ENG manufacturers and distributors. Petitioner argues that this particular training is "adequate" since it is accepted by the American Academy of Audiology. P. Br. at 2. Petitioner contends that the Carrier is imposing a direct supervision requirement by not recognizing the training administered by ENG manufacturers and distributors. According to Petitioner, the Carrier is circumventing federal regulations by requiring their technicians to be directly supervised by physicians when performing ENG testing. P. Br. at 2.

CMS contends that Petitioner does not meet the statutory or regulatory requirements to receive Medicare reimbursement for the services provided by its ENG technicians. CMS Br. at 1. CMS points out that Petitioner provided the names of two technicians in its July 2004 enrollment application indicating that neither technician was licensed or certified by the Commonwealth. CMS also suggests that Petitioner did not indicate on the enrollment application that it employed an audiologist. CMS Br. at 3. CMS argues that pursuant to 42 C.F.R. § 410.33(a)(2)(ii) diagnostic audiology testing, including ENG testing, is covered by Medicare when performed by a qualified audiologist. CMS Br. at 2. According to CMS, the law clearly provides that the only way an IDTF can obtain Medicare reimbursement in the Commonwealth of Pennsylvania for the performance of ENG testing is if the services are performed by a qualified and appropriately licensed audiologist. CMS Br. at 6.

I find the legal arguments advanced by CMS to be compelling. The law at section 1861(l)(2) of the Act provides that “the term ‘audiology services’ means such hearing and balance assessment services furnished by a qualified audiologist as the audiologist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law), as would otherwise be covered if furnished by a physician.” The term “qualified audiologist” is defined by the Act as an individual with a master’s or doctoral degree in audiology who is licensed by the state or if the state does not license audiologists, completes the 350 hours of supervised clinical practicum and 9 months of supervised full-time audiology services after earning a master’s or doctoral degree. Act, section 1861(l)(3)(B)².

Pursuant to 42 C.F.R. § 410.33(a)(2)(ii) the diagnostic tests which Petitioner intends to administer must be performed by a qualified audiologist if furnished by a non-hospital testing entity. I find that CMS is correct in its assertion that if hearing and balance diagnostic tests, such as ENG tests, are performed by an IDTF it is mandatory that the testing must be performed by a qualified audiologist. According to CMS, the two technicians listed on Petitioner’s enrollment application were to perform the diagnostic testing. CMS Br. at 3; CMS Ex. 12, at 16. The two technicians are not qualified licensed audiologists and are not represented by Petitioner as such. However, Petitioner contended that because these technicians completed training programs provided by the manufacturers and distributors of the testing equipment, they should be considered qualified to perform the testing. Petitioner asserts that it should be reimbursed under the physician fee schedule for the services provided by the technicians. Petitioner’s position is not supported by the law. Petitioner’s technicians cannot be considered qualified to perform the diagnostic testing that Petitioner intends to administer. The fact that

² Pennsylvania licenses audiologists, therefore subsection (i) of Act, section 1861(l)(3)(B) applies in this case.

Petitioner's technicians received training to use the diagnostic testing equipment from the manufacturers and distributors of the equipment is irrelevant. The regulations are clear that ENG tests as well as other hearing and balance diagnostic testing must be performed by a physician or an audiologist as defined by section 1861(l)(3)(B) of the Act. The fact that neither technician is a physician or a qualified audiologist is not disputed by Petitioner. Therefore, because Petitioner failed to satisfy the requirement that a physician or qualified audiologist perform the diagnostic tests, its application for enrollment as an IDTF was appropriately denied.

V. CONCLUSION

Petitioner has failed to establish that its technicians fit within or satisfy the requirements of the definition of an audiologist. Thus, Petitioner does not qualify for a Medicare Part B provider enrollment number as an Independent Diagnostic Testing Facility. I therefore affirm the CMS's denial of Petitioner's enrollment application.

/s/ Alfonso J. Montano
Administrative Law Judge