Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: February 19, 2010
US Ultrasound,	
Petitioner,	Civil Remedies CR1982 App. Div. Docket No. A-09-117
- v. -	
	Decision No. 2302
Centers for Medicare & Medicaid Services.	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

US Ultrasound appeals the July 31, 2009 decision of Administrative Law Judge Richard J. Smith granting summary judgment in favor of the Centers for Medicare & Medicaid Services (CMS). US Ultrasound, DAB CR1982 (2009) (ALJ Decision). The ALJ upheld CMS's denial of US Ultrasound's applications to enroll in Medicare as an Independent Diagnostic Testing Facility (IDTF) supplier.

We uphold the ALJ Decision. US Ultrasound does not challenge the ALJ's determination that, at the time US Ultrasound applied to enroll and thereafter, it did not meet Medicare enrollment requirements for an IDTF for either of the locations for which it applied. Based on this determination, the ALJ properly concluded that CMS was authorized to deny US Ultrasound's applications. The ALJ also properly concluded that he had no authority to grant US Ultrasound's request for equitable relief related to the costs of IDTF services provided to Medicare beneficiaries.

Standard of Review

The standard of review on a disputed factual issue is whether the ALJ decision is supported by substantial evidence in the record as a whole. The standard of review on a disputed issue of law is whether the ALJ decision is erroneous. http://www.hhs.gov/dab/divisions/appellate/guidelines/prosupenrolmen.html.

Background

In 2008, US Ultrasound filed two CMS-855B enrollment applications with Wisconsin Physicians Service Insurance Corporation (WPS), a Medicare contractor responsible for processing prospective suppliers' applications. In these applications, US Ultrasound requested separate approvals as an IDTF in Missouri and in Kansas. An IDTF performs "diagnostic procedures" including ultrasounds. 42 C.F.R. § 410.33(a)(1). An IDTF is classified as a supplier (as opposed to a provider) under Medicare. 42 C.F.R. §§ 400.202; 498.2.

US Ultrasound represented before the ALJ that it intended to operate as an IDTF by marketing mobile ultrasound services through a contractual arrangement with a company called Alliance Radiology (Alliance). CMS Ex. 6, at 157, 234-52; P. Ex. 4 (letter of January 19, 2009). Under that contract, which was included with US Ultrasound's applications, Alliance (which owned the relevant ultrasound equipment and employed the technicians who maintained and operated the equipment and the supervising doctors) agreed to "provide both technical and professional services" for the mobile ultrasound procedures and services listed in an attached "Scope of Services Scheduled." CMS Ex. 6, at 234. The attached schedule indicated that Alliance would provide ultrasound procedures in "nursing homes, rehabilitation hospitals, and home health"; "provide services as Medical Director at no cost to US UltraSound"; "provide and supervise technical staff"; provide a "complete listing of all equipment and serial numbers that will be utilized in providing services for this agreement"; "make available all maintenance reports on each piece of equipment that may be needed for Medicare"; "at [Alliance's] expense keep equipment in well maintained and working order"; and "at [Alliance's] expense will have equipment calibrated and certified when needed." CMS Ex. 6, at 253. US Ultrasound agreed to pay Alliance a percent of its "net monthly collections" for ultrasound services provided by Alliance "as directed by US Ultrasound" in defined geographic areas. Id.

US Ultrasound also represented before the ALJ that it consulted with its prior Medicare contractor about this arrangement before filing the IDTF applications, that it included copies of the contract with Alliance as part of its IDTF applications to WPS, and that it repeatedly informed WPS reviewers "what we were doing and how the services were being performed." P. Ex. 4 (letters dated January 19 and 28, 2009); P. letter to Board of January 28, 2010. On August 8, 2008, WPS conducted an onsite review of US Ultrasound's offices as part of its reviews of the applications. P. Ex. 4 (letter of January 19, 2009, at 2).

On appeal before the Board, the president of US Ultrasound stated that, after the onsite review, he "followed up weekly with WPS to find out when I could start to bill the services we were providing." P. letter of January 28, 2010; see also P. Ex. 4 (letter of January 19, 2009, at 2). He also made the following statement (for the first time) about his interaction with WPS:

> To bill Medicare, I had to have in writing the provider numbers to bill electronically. On September 11, 2008, I advised WPS that I had to have something so I could set up to bill, but I still agreed not to bill them until I received an approval from WPS.

P. letter of January 28, 2010 (emphasis added).

On September 11, 2008, the day of the conversation described above, WPS sent US Ultrasound letters with respect to the two enrollment applications providing it with Provider Transaction Access Numbers (PTANs). The letters also stated that US Ultrasound's applications had been approved and that the effective date for its participation in Medicare as an IDTF was June 15, 2008. CMS Ex. 3. US Ultrasound indicated in its brief before the ALJ that it never actually submitted bills to Medicare for IDTF services provided under its arrangement with Alliance. P. Response to CMS Motion for Summary Judgment (MSJ) at 2. [1]

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[1] The record before the ALJ did not disclose the conversation in which US Ultrasound's president indicates that he told WPS that he wanted a provider number to "set up" billing but that he agreed not to bill until approval was received. Therefore, the ALJ did not take into account this new information when he commented that US Ultrasound made no "misstatement or mistake" but rather acted "perfectly reasonably in relying on [WPS's September 11] erroneous assurance" of

(Continued. . .)

In letters dated November 20, 2008, however, WPS notified US Ultrasound that WPS would "not be taking any action to process [these] application[s]" because:

> After further review of your application, it was determined that we cannot issue/release your Medicare PTAN. The equipment that you are listing on your application is owned by Alliance Radiology, they are also responsible for the calibration and maintenance of the equipment. The agreement that was inclosed [sic] indicates that Alliance Radiology provides the technical and professional services. Alliance Radiology provides technical staff, equipment and the transportation. US Ultrasound pays Alliance Radiology a professional fee for the professional services (billing, scheduling and patient records). Alliance Radiology is the entity that will need to be set up as the Independent Diagnostic Testing Facility.

CMS Ex. 4; P. Ex. 2.

In letters dated January 6, 2009, WPS informed US Ultrasound that its requests to enroll in Medicare were denied. CMS Ex. 1. WPS stated that US Ultrasound did not "meet the conditions of enrollment or meet the requirements to qualify as a Medicare provider/supplier" because the "[e]ntity performing the services on the [Kansas or Missouri] application is not the entity who is enrolling." A contractor hearing officer upheld WPS's determination denying approval of the applications. CMS Ex. 2; ALJ Decision at 3.[2] Thereafter, US Ultrasound requested an ALJ hearing.

Before the ALJ, CMS moved for summary judgment, arguing that US Ultrasound's applications were properly denied because US Ultrasound "failed to comply substantially with federal requirements applicable to the enrollment of an IDTF." CMS

(Continued. . .)

Medicare enrollment. ALJ Decision at 8.

[2] The record contains only one of the hearing officer's decisions. The ALJ stated, and the parties do not dispute, however, that "there are no material differences in the facts regarding the two locations and Petitioner's enrollment has been denied for both locations." ALJ Decision at 3.

Motion for MSJ at 5. Specifically, CMS alleged that US Ultrasound did not meet the definition of "supplier" under 42 C.F.R. § 400.202, which provides that a supplier is an entity that "furnishes health care services under Medicare." CMS MSJ at 5-6 (emphasis added). CMS alleged that US Ultrasound did not furnish services within the meaning of section 400.202. Id. at 6.

CMS argued further that its construction of section 400.202 was supported by 42 C.F.R. § 410.33(g), which requires IDTFs to meet a range of standards related to the actual furnishing of independent diagnostic testing services and that US Ultrasound did not meet these requirements either. Id. CMS pointed to other Medicare authority supporting its position that, absent authority to the contrary, a supplier is expected to be the entity furnishing the services. CMS cited certification standards governing suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) found at 42 C.F.R. § 424.57(c). The DMEPOS certification standards establish an express exception that allows DMEPOS to contract with other companies in furnishing equipment and services. Id. at 7. Also, CMS cited its payment manual, which "contains provisions allowing a physician to submit a claim for the technical component of diagnostic tests purchased from another physician provider or other type of supplier, and for a diagnostic test supplier to make a claim for the purchase [of] a physician's test interpretation" but requires "the claiming entity to have provided . . . either the technical or professional element of service." Id. at 7 n.4, citing Medicare Claims Processing Manual, PUB 100-04, Ch. 13, § 20.2.4.2; (available at http://www.cms.hhs.gov/manuals/downloads/clm104c13.pdf). CMS argued that no exception applied to IDTFs and that US Ultrasound did not even claim to provide either the technical or professional elements of the services.

The ALJ granted CMS's motion for summary judgment and upheld CMS's denials of US Ultrasound's applications.

Analysis

1. The ALJ did not err in concluding that CMS had authority to deny US Ultrasound's applications.

US Ultrasound has failed to demonstrate any error in the ALJ's conclusion that US Ultrasound did not meet the Medicare definition of "supplier." Section 1861(d) of the Social Security Act (Act) (42 U.S.C. § 1395x(d)) defines a supplier as an entity that "furnishes items or services under [Medicare]."

See also 42 C.F.R. § 400.202. The ALJ agreed with CMS that US Ultrasound was not a supplier because, under US Ultrasound's contract with Alliance, it "did not own any [ultrasound] equipment, was not responsible for the calibration and maintenance of the equipment, and was not responsible for either technical (actually performing or administering the test) or professional (reading or interpreting the data obtained by a test) services" and, therefore, did not "furnish" services. ALJ Decision at 7-8. US Ultrasound did not, and does not, dispute CMS's construction of the term "furnish" or argue that, under its arrangement with Alliance, it furnished services within the meaning of section 1861(d) of the Act or 42 C.F.R. § 400.202.

US Ultrasound has also failed to demonstrate any error in the ALJ's conclusion that US Ultrasound did not meet the regulatory requirements for IDTFs as set forth at 42 C.F.R. § 410.33(g). ALJ Decision at 5, 7-8. Section 410.33(g) requires IDTFs to meet a range of standards related to the furnishing of independent diagnostic testing services. These include maintaining a physical facility with equipment or mobile units "appropriate to the services designated on the enrollment application," maintaining testing equipment, and having "technical staff on duty with the appropriate credentials to perform tests." US Ultrasound did not, and does not, dispute CMS's construction of section 410.33(g) or argue that, under its arrangement with Alliance, it met the requirements of that section.

Further, US Ultrasound has failed to demonstrate any error in the ALJ's conclusion that, because US Ultrasound never met the applicable Medicare requirements, CMS had the authority to deny US Ultrasound's IDTF applications. ALJ Decision at 4-5, 8. The ALJ relied on 42 C.F.R. § 424.530(a)(1). That section provides that CMS may deny a supplier's enrollment application if --

> [t]he . . . supplier at any time is found not to be in compliance with the Medicare enrollment requirements described in this section or on the applicable enrollment applications to the type of . . . supplier enrolling and has not submitted a plan of action as outlined in part 488 of this chapter.

Additionally, 42 C.F.R. 410.33(h) authorizes CMS to deny these applications. It provides, in pertinent part:

> *Failure to meet standards.* If an IDTF fails to meet one or more of the standards in paragraph (g) of this section at the time of enrollment, its enrollment will be denied.

(Emphasis added.) The preamble for the notice adopting section 410.33(h) supports our reading of this regulation as permitting CMS to deny an application previously approved in error where CMS discovers the supplier did not meet IDTF requirements at the time of enrollment. CMS stated:

> [A]t § 410.33(h), we proposed that if an IDTF fails to meet one or more of the standards at the time of enrollment or at the time of re-enrollment, then its enrollment application would be denied. Also, if at any time we determine that an enrolled IDTF no longer meets the performance standards, its billing privileges would be revoked.

71 Fed. Reg. 69,784, 69,699 (2006) (emphasis added). US Ultrasound did not, and does not, dispute that it did not meet the IDTF standards at the time of enrollment.

Before the ALJ, US Ultrasound argued that CMS had "approved" its IDTF enrollment application and granted it billing privileges on September 11, 2008, and, therefore, CMS could not "deny" the previously approved application. Response to CMS MSJ at 3-4, 4 n.4. US Ultrasound argued below that CMS was required to "revoke" (rather than deny) US Ultrasound's enrollment and billing privileges under 42 C.F.R. § 424.535. Id.[3]

US Ultrasound failed to demonstrate any error in the ALJ's rejection of this argument. ALJ Decision at 6. Sections 424.530(a)(1) and 410.33(h) allow CMS to deny applications for enrollment, without regard to CMS's prior actions on those applications, where entities did not meet the applicable requirements at the time of enrollment. Moreover, CMS's use here of denials, as opposed to revocations, could have benefitted US Ultrasound in the sense that revocations would have resulted in an automatic "re-enrollment bar" of a minimum of one year for US Ultrasound and its delegated officials and authorizing officials. 42 C.F.R. § 424.535(c).

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[3] US Ultrasound argues that, if CMS had revoked its enrollment, it would have been entitled to Medicare reimbursement for services provided prior to the revocation. P. Response to CMS MSJ at 3-4, 4 n.4. CMS disputes US Ultrasound's position. CMS Response to Order to Develop the Record at 2-3. Since we conclude that CMS had authority to deny the applications, we do not discuss the potential consequences of revocation.

We therefore find that the ALJ's conclusion that CMS had legal authority to deny US Ultrasound's applications was free of legal error.

2. The ALJ did not err by rejecting US Ultrasound's request for equitable relief.

US Ultrasound asserts that the result in this case was inequitable because its reliance on WPS's actions caused it to suffer financial loss in the form of services rendered and costs incurred for start-up and marketing. Response to CMS MSJ at 2; P. Ex. 4 (letters of January 19, 2009, at 3, and of January 28, 2009, at 2); P letter of January 28, 2010. The ALJ expressed sympathy with US Ultrasound's situation but concluded that he lacked authority to require enrollment of US Ultrasound on equitable grounds when it did not meet the legal requirements. ALJ Decision at 6, 8.

Neither the ALJ nor the Board is authorized to provide equitable relief by reimbursing or enrolling a supplier who does not meet statutory or regulatory requirements. ALJ Decision at 7; see Regency on the Lake, DAB No. 2205 (2008). Moreover, to the extent that US Ultrasound is asking that CMS be equitably estopped from denying reimbursement for services furnished by Alliance, estoppel against the federal government, if available at all, is presumably unavailable absent "affirmative misconduct," such as fraud, by the federal government. See, e.g., Pacific Islander Council of Leaders, DAB No. 2091 (2007); Office of Personnel Management v. Richmond, 496 U.S. 414, at 421 (1990). US Ultrasound makes no allegations of such affirmative misconduct. Moreover, as the Board has previously observed, even when government agents have given private individuals advice that directly contradicts federal regulations, the Supreme Court has not permitted estoppel. Lower Brule Sioux Tribe, DAB No. 1758 (2000); Enterprise for Progress in the Community, DAB No. 1558 (1996); Texas Dept. of Human Services, DAB No. 1344, at 9 (1992) (and cases cited therein).

Conclusion

For the foregoing reasons, we affirm the ALJ Decision.

/s/
Judith A. Ballard

/s/
Constance B. Tobias

/s/
Leslie A. Sussan
Presiding Board Member