Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Ultra-X Imaging,	)	Date: February 18, 2010
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-09-360
	)	Decision No. CR2066
The Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) that Petitioner, Ultra-X Imaging, was not in compliance with the Medicare program's conditions for coverage for portable x-ray suppliers.

I. Applicable Law

The Social Security Act (Act) sets forth requirements for providers and suppliers participating in the Medicare program, and authorizes the Secretary of Health and Human Services to promulgate regulations implementing those statutory provisions. Act § 1102. Medicare reimbursement for portable x-ray supplier services is authorized under section 1861(s)(3) of the Act. The Secretary's regulations governing portable x-ray suppliers, and the conditions for coverage for such services, are found at 42 C.F.R. Part 486, Subpart C. To participate in the Medicare program, a prospective supplier must be in compliance with the applicable conditions. 42 C.F.R. § 488.3. The Secretary may refuse to approve a prospective provider or supplier if it is unable to give satisfactory assurance of compliance with the requirements of Title XVIII of the Act. 42 C.F.R. § 489.12(a)(4); *see also* 42 C.F.R. §§ 489.1(d), 489.13.

The Secretary contracts with state agencies to conduct surveys to determine whether providers or suppliers are in compliance with Medicare conditions for coverage. Act § 1864(a); 42 C.F.R. § 488.20. State survey agencies are required to certify that a provider or supplier is not in compliance with the conditions for coverage "where the deficiencies are of such a character as to substantially limit the provider's or supplier's capacity to furnish adequate care or which adversely affect the health and safety of patients." 42 C.F.R. § 488.24(b). A supplier found deficient with one or more standards under the conditions for coverage may participate in Medicare only if it has submitted an acceptable plan of correction within a reasonable period of time and its deficiencies, individually or in combination, do not jeopardize patient health or safety or seriously limit its capacity to render adequate care. 42 C.F.R. § 488.28. However, when a supplier is found out of compliance with a condition-level requirement, as opposed to a standard, the regulations do not afford such an opportunity. 42 C.F.R. § 488.28(c).

The critical date for establishing compliance is the survey date, not a subsequent date of alleged compliance. CMS relies on the findings of the State survey agency in making its determinations, and the survey agency's findings necessarily relate to the status of a provider or supplier as of the date of the survey. As the Departmental Appeals Board has noted, to rely "on a later date after the survey as the dispositive date for determining compliance . . . could cause a never-ending cycle of resurveys based on unsubstantiated claims of compliance" on a later date. *Carmel Convalescent Hospital*, DAB No. 1584 (1996).

If CMS determines that a prospective supplier of portable x-ray services is not in compliance with conditions for coverage, the prospective supplier may request a hearing before an Administrative Law Judge. 42 C.F.R. §§ 488.24(c); 498.2; 498.3(b)(5). The hearing before an administrative law judge is a *de novo* proceeding. *Anesthesiologists Affiliated, et al*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991). CMS must establish a prima facie case by introducing enough evidence to establish a fact or raise a presumption unless disproved or rebutted. *See Hillman Rehabilitation Center*, DAB No. 1611, at 8 (1997), *aff'd Hillman Rehab. Ctr. v. U.S. Dep't of Health & Human Services*, No. 98-3789 (GEB) (D.N.J. May 13, 1999). To prevail, Petitioner must overcome CMS's showing by a preponderance of the evidence. *Evergreene Nursing Care Center*, DAB No. 2069, at 7-8 (2007); *Hillman Rehabilitation Center*, DAB No. 1611.

II. Background

Petitioner is a portable x-ray service located in Belleville, Michigan. Following an initial certification survey conducted by the Michigan Department of Community Health (State agency) on September 4, 2008, Petitioner was found to be out of compliance with three conditions for coverage: 42 C.F.R. § 486.102, supervision by a qualified physician; 42 C.F.R. § 486.104, qualified technologist; and 42 C.F.R. § 486.108, safety standards. On November 12, 2008, CMS notified Petitioner that it did not meet the requirements for

participation in the Medicare program because of its noncompliance with those conditions for coverage. On December 3, 2008, Petitioner requested reconsideration of the CMS determination. On January 30, 2009, CMS affirmed its original determination denying Petitioner certification as a supplier of portable x-ray services.

On March 18, 2009, Petitioner timely requested a hearing. Specifically, Petitioner asserts that CMS's determinations were based on faulty or insufficient information. Hearing request at 1.

The case was assigned to me for a hearing and decision. The parties submitted Reports of Readiness for Hearing. On July 8, 2009, I held a pre-hearing telephone conference and explained to the parties that the case could be decided based on an in-person hearing or written submissions. Both parties chose to have the case decided based on written submissions and I set forth a briefing schedule that gave Petitioner another opportunity to request an in-person hearing after reviewing CMS's brief. July 10, 2009 Order. CMS submitted a brief, and Petitioner submitted a letter in lieu of a brief stating that it had submitted a new enrollment application to CMS and that it would base its case on the information that it had already provided.[1] CMS submitted 12 exhibits (CMS Exs. 1-12). Petitioner submitted eight exhibits: four attachments and four letters. I have marked the four attachments as Petitioner's Exhibits 1-4 (P. Exs. 1-4), and the four letters as P. Exs. 5-8, and have attached an exhibit list of Petitioner's exhibits to this decision.

III. Issue

Whether CMS had a basis to deny Petitioner certification in the Medicare program as a portable x-ray supplier.

IV. Discussion

A. Petitioner was not supervised by a qualified physician at the time of the survey, as required by 42 C.F.R. § 486.102.

The regulations require, as a condition for coverage, that portable x-ray services be provided under the supervision of a qualified physician. 42 C.F.R. § 486.102. The physician supervisor must be a licensed doctor of medicine or a licensed doctor of osteopathy qualified by advanced training and experience in the use of x-rays for diagnostic purposes. 42 C.F.R. § 486.102(a). Additionally, the supervising physician must certify annually that he or she periodically checks the procedural manuals and

[1] As I explained during the July 8, 2009 pre-hearing conference, I cannot review a decision by the State survey agency as to when to conduct an initial survey of a prospective provider or supplier. 42 C.F.R. § 498.3(d)(15).

observes the operators' performance, that he or she has verified that equipment and personnel meet applicable Federal, State, and local licensure and registration requirements, and that safe operating procedures are used. 42 C.F.R. § 486.102(b).

In this case, Petitioner was not able to provide Surveyor Rick Brummette with clear evidence that it had any qualified physician in place and performing the required supervision activities. Petitioner's part-owner and employee, William Hughes, informed Surveyor Brummette that Petitioner had ended its relationship with its previous supervising physician, Dr. Herbert Weisenthal, around January 2008, and that it was in the process of bringing in a new supervising physician. CMS Ex. 9, at 3 (Brummette Decl. ¶ 14). While Mr. Hughes mentioned two names, Dr. Goldsmith and Dr. Collado, to Surveyor Brummette, he was unable to provide any documentation that either of the individuals had a formal relationship with Petitioner or had performed any supervisory work. CMS Ex. 9, at 3-4 (Brummette Decl. ¶ 14). Mr. Hughes did not mention Dr. Sadar Zamen during the interview. CMS Ex. 9, at 4 (Brummette Decl. ¶ 16). Mr. Hughes was also unable to provide any documentation showing that either of the physicians were qualified by advanced training and experienced as the regulations require.

Although Petitioner contends that it showed Surveyor Brummette the credentials of its new physician, Sadar Zamen, M.D., it has not presented any evidence here that Dr. Zamen was employed as its supervising physician at the time of the survey. Hearing Request at 1. The only document that Petitioner offers to show that it employs Dr. Zamen is a statement signed on September 24, 2008, indicating that Dr. Zamen is performing the duties of a supervising physician. P. Ex. 1D; CMS Ex. 8, at 11. This statement, signed 20 days after the survey, does not show that Dr. Zamen was a supervising physician at the time of the survey. Moreover, although Petitioner has provided information showing Dr. Weisenthal's credentials, it has not submitted any evidence to rebut the statement of its own employee that its relationship with the doctor ended around January 2008.

Therefore, based on the evidence that the parties have submitted, it appears that at the time of the survey Petitioner was not in compliance with this condition for coverage.

B. Petitioner did not employ qualified technicians, have an orientation program that met regulatory requirements, or maintain records showing that employees received adequate health supervision at the time of the survey, as required by 42 C.F.R. § 486.104.

A provider of portable x-ray services must employ qualified technicians; have an orientation program for personnel based on a procedural manual that includes, among other things, instructions on precautions that should be taken to protect an individual supporting a patient from unnecessary exposure to radiation; and maintain employee

records that include evidence that each employee is qualified for his or her position by means of training and experience and that each employee receives adequate health supervision. 42 C.F.R. § 486.104.

Technician qualifications

Federal regulations require that technicians complete a program of formal training not less than 24 months in duration from an approved school or have a bachelor's or associate degree in radiologic technology. 42 C.F.R. § 486.104(a)(1).

Mr. Hughes informed Surveyor Brummette that there were three technicians on staff at the facility. However, Mr. Hughes could not provide any documentation to show that any of these three individuals met the training requirements. CMS Ex. 9, at 4-5 (Brummette Decl. ¶¶ 18-19). He was unable to provide documentary evidence showing that Melvin Turner had attended an x-ray technician training program that was at least 24 months in duration. He was unable to produce any evidence of his own qualifications or his employee record. While Mr. Hughes was unable to provide the name of the third technician (referred to as Technician 2 in Surveyor Brummette's declaration) or any documentation showing his qualifications, Mr. Hughes told the surveyor that Petitioner was still in the process of hiring Technician 2, so the lack of documentation regarding Technician 2 is not surprising and does not indicate that Petitioner was out of compliance with the standard. CMS Ex. 9, at 4-5 (Brummette Decl. ¶ 19).

Petitioner has submitted several documents concerning its two technicians' qualifications. P. Ex. 2A-B; CMS Ex. 8, at 14-17, 19-26. Mr. Turner appears to meet the regulatory requirements. However, it is unclear whether Mr. Hughes meets the requirements. Petitioner has produced several letters suggesting that Mr. Hughes worked as a radiology technician from approximately 1994-1998 and 2006-2008. P. Ex. 2D-G; CMS Ex. 8, at 19-22. Petitioner has also submitted a certificate and related documentation stating that in June 1992, Mr. Hughes completed the "necessary clock hours of technical instruction in X-ray Technician." P. Ex. 2H-J; CMS Ex. 8, at 23-26. But neither the certificate nor the attached documentation explains how many hours of instruction were necessary for completion. From the other documents, it appears that Mr. Hughes took two courses during one semester. P. Ex. 2I-J; CMS Ex. 8, at 24-26. Although Petitioner contends that CMS accepts experience on the job as valid credentialing, the regulations are clear that on the job credentialing applies only to technicians who completed their training prior to 1966. Petitioner's Report of Readiness at 2; 42 C.F.R. § 486.104(a)(2)-(3). The course work submitted here, even with Mr. Hughes' experience, is not sufficient to meet the regulatory requirements.[2]

[2] Mr. Brummette states in his declaration that Mr. Hughes had been determined permanently ineligible for registry by the American Registry of Radiologic Technologists by reason of Misrepresentation. CMS Ex. 9, at 5 (Brummette Decl. ¶ 21); CMS Ex. 4.

(continued . . .)

Orientation program

A supplier of portable X-ray services must have an orientation program for personnel, based on a procedural manual that is available to all members of the staff, incorporates relevant portions of professionally recognized documents, and includes instruction in 12 specified areas. These areas include the hazards of excessive exposure to radiation and precautions to be followed to protect an individual supporting a patient from unnecessary exposure to radiation. 42 C.F.R. § 486.104(b).

In his declaration, Surveyor Brummette states that at the time of the survey, Petitioner was unable to provide him with any evidence that it had an orientation program or that any of the employees has participated in an orientation program. Mr. Hughes told Surveyor Brummette that Petitioner's orientation program was an "on the job kind of thing." CMS Ex. 9, at 5 (Brummette Decl. ¶¶ 22-23). Surveyor Brummette noted that he could not find any documentary evidence that Petitioner had trained its employees regarding precautions to be followed to protect an individual supporting a patient from unnecessary exposure to radiation as required by 42 C.F.R. § 486.104(b)(2). CMS Ex. 9, at 5 (Brummette Decl. ¶ 23).

Petitioner has produced two signed documents listing the regulatory requirements for the manual and stating that it has an orientation program for technical personnel based on that manual and that the employees have taken the orientation. P. Ex. 3A-B; CMS Ex. 8, at 27-29. However, these documents are not persuasive evidence of Petitioner's orientation program. Even if I found that these documents were persuasive to show an orientation program existed, they were signed on September 24, 2008, twenty days after the survey occurred. Petitioner has not produced its procedural manual or any other existing policies or instructions regarding the precautions that should be taken to protect an individual supporting a patient from unnecessary exposure to radiation.

Employee records

Employee records must be maintained and include evidence that each employee is qualified for his or her position by means of training and experience and that employees receive adequate health supervision. 42 C.F.R. § 486.104(c).

As noted above, at the time of the survey, Petitioner could not produce any records to show that its employees were qualified. Even though it has now produced evidence that shows that Dr. Weisenthal, Dr. Zamen and Mr. Turner are qualified, it did not maintain its records so that they could be reviewed at the time of the survey. Additionally, even though it provided these employees' qualifications, Petitioner still has not offered

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(. . . continued)

While registry with this organization is not a requirement, Petitioner chose not to respond to any of CMS's exhibits, including CMS Exhibit 4.

evidence showing that Dr. Zamen was employed at the time of the survey nor has it offered any evidence to rebut Mr. Hughes' statement that it ended its relationship with Dr. Weisenthal in January 2008. Again, Petitioner has not provided documents or records showing that Mr. Hughes meets the regulatory training requirements.

Surveyor Brummette stated that he could find no documentation that Petitioner had provided any health supervision for its employees. 42 C.F.R. § 486.104(c); CMS Ex. 9, at 5 (Brummette Decl. ¶ 24). Petitioner has not produced any evidence to show that it provided such supervision.

Therefore, based on the evidence before me, I conclude that Petitioner was out of compliance with this condition for coverage because Petitioner has not shown: that its technician, Mr. Hughes, met the federal training requirements; that it had an orientation program at the time of the survey that included instruction on precautions to protect an individual supporting a patient from unnecessary exposure to radiation; or that it maintained records showing its employees' qualifications and health supervision for them.

C. The evidence establishes that Petitioner was not in compliance with safety standards at the time of the survey, as required by 42 C.F.R. § 486.108.

Providers of portable x-ray services must conduct x-ray examinations through the use of equipment that is free of unnecessary hazards for patients, personnel, or other persons in the immediate environment. The operating procedures must provide the minimum radiation exposure to patients, personnel, or other persons in the immediate environment. 42 C.F.R. § 486.108.

Petitioner has submitted evidence acknowledging that it was not in compliance with safety standards at the time of the survey. P. Ex. 4A-D; CMS Ex. 8, at 3-5. Following a State radiation safety examination conducted on September 10, 2008, by Cathy Clark, Health Physicist for the State agency, Surveyor Brummette found that Petitioner was out of compliance with the safety standards for tube housing and devices to restrict the useful beam, personnel monitoring, and the exposure control switch. CMS Ex. 9, at 6-7 (Brummette Decl. ¶¶ 26-29); CMS Ex. 1, at 8-11.

<u>Tube housing and devices to restrict the useful beam</u>

Regulations require that the x-ray equipment's tube housing is of diagnostic type and that diaphragms, cones, or adjustable collimators capable of restricting the useful beam to the area of clinical interest are used and provide the same degree of protection as is required of the housing. 42 C.F.R. § 486.108(a).

Surveyor Clark explained in her declaration that during an inspection, she observes x-ray equipment for compliance with safety standards regarding the tube housing, devices to restrict the useful beam, and the exposure control switch. The purpose of the standards is to ensure that the x-ray beam is restricted to the clinical area of interest and that the equipment is operated in a way to prevent unnecessary radiation exposure to the operator, patient, or others. CMS Ex. 11, at 2-3 (Clark Decl. ¶ 10).

During her inspection, Surveyor Clark tested and observed two machines. The collimator field size indicators on both machines were not accurate within two percent of the source-to-image distance. CMS Ex. 5. In x-ray equipment, a collimator narrows and filters the beam of particles or waves. CMS Ex. 11, at 3 (Clark Decl. ¶ 12). One of the machines' light fields was shifted to the side two inches on one side and one inch on the other. The dials on both machines, which are used to set the x-ray field, were inaccurate outside the two percent range meaning that the useful radiation beam was not appropriately restricted.[3] CMS Ex. 11, at 3 (Clark Decl. ¶ 13). Inaccurate collimation can lead to inaccurate clinical images and scattered radiation, which could result in potential harm to the patient, operator, and others. CMS Ex. 11, at 3 (Clark Decl. ¶ 14).

Petitioner has not argued that it was in compliance with this requirement at the time of the survey or the examination, but has offered evidence that it subsequently corrected the violation. P. Ex. 4B-D; CMS Ex. 8, at 3-5.

Personnel monitoring

Suppliers of portable x-ray services must provide each x-ray operator with a device which can be worn to monitor radiation exposure. The device is evaluated for radiation exposure to the operator at least monthly and the supplier maintains appropriate records of the device's radiation exposure measurements for each individual. 42 C.F.R. § 486.108(j).

Dosimeters measure an individual's exposure to a hazardous environment, particularly when the hazard is cumulative over a long period of time. Dosimeters have a specific wear period and must be rotated in and out of use so that they can be measured for radiation exposure. CMS Ex. 11, at 4 (Clark Decl. ¶ 16).

Petitioner was not able to provide Surveyor Clark with all the personnel dosimetry reports. It could not provide any evidence that dosimeters had been issued for the period of January 15 through April 14, 2008. CMS Ex. 11, at 4 (Clark Decl. ¶ 17). The dosimeters that were in use at the time of the September 10 examination should have

[3] Two percent is the standard used by the State agency. Mich. Comp. Laws § 333.13521; Mich. Admin. Code R. 325.5351-325.5353. It is not listed at 42 C.F.R. § 486.108(a) and I do not consider it dispositive in determining Petitioner's compliance with this standard.

been returned for evaluation on July 15, 2008, as their assigned wear period had ended. Petitioner has other dosimeters available for the wear period of July 15 through October 14, 2008, but they had not been issued to employees. CMS Ex. 11, at 4 (Clark Decl. ¶ 18).

Again, Petitioner has not argued that it was in compliance with this requirement at the time of the survey or the examination, but has offered evidence that it subsequently corrected the violation. P. Ex. 4B-D; CMS Ex. 8, at 3-5.

Exposure control switch

Regulations require that the exposure control switch be of the dead-man type and arranged so that the operator can stand at least six feet from the patient and well away from the useful beam. 42 C.F.R. § 486.108(e)

Although Surveyor Clark observed one of Petitioner's technicians, Mr. Hughes, stand only three feet from the primary x-ray beam, it is not clear that Petitioner was out of compliance with this standard because the machine had a six-foot cord. CMS Ex. 11, at 4 (Clark Decl. ¶ 19).

Because it has not asserted that it was in compliance and based on the evidence before me, I conclude that Petitioner was not in compliance with the condition for coverage, Safety standards, at the time of the survey.

V. Conclusion

Based on my review of all the evidence in this case, I sustain the determination by CMS that Petitioner was not in compliance with three conditions for coverage related to health and safety as specified by the Secretary. Act § 1861(s)(3); 42 C.F.R. §§ 102, 104, 108. Petitioner's deficiencies, individually and in combination, substantially limited its ability to furnish adequate care and could have adversely affected the health and safety of patients at the time of the survey. 42 C.F.R. § 488.24(b). The Secretary may refuse to enter into an agreement with a prospective provider or supplier if it is unable to give satisfactory assurance of compliance with the requirements of Title XVIII of the Act. 42 C.F.R. § 489.12(a). Here, Petitioner has not given satisfactory assurance of its compliance at the time of the survey. Thus, CMS was authorized to deny Petitioner's certification as a supplier of portable x-ray services.

/s/
Alfonso J. Montaño
Administrative Law Judge