Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Centro Radiologico Rolon, Inc.,

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-13-548

Decision No. CR3136

Date: February 28, 2014

DECISION

The Centers for Medicare & Medicaid Services (CMS) revoked the Medicare enrollment and billing privileges of Petitioner, Centro Radiologico Rolon, Inc., an independent diagnostic and testing facility (IDTF) located in Puerto Rico. Petitioner appealed. As discussed below, I find Petitioner did not comply with Medicare requirements because its employees did not have the proper qualifications, and it did not properly notify CMS of a change in its supervisory physician. Therefore, I affirm CMS's revocation.

I. Background

This case has a long history. Petitioner initially was notified that its billing privileges were being revoked in September 2011 and a reconsideration decision on that determination was issued on December 15, 2011.[1] Petitioner timely submitted a request

[1] Pursuant to First Coast Service Options, Inc.'s (FCSO's) September 19, 2011 letter initially proposing revocation, Petitioner submitted a Corrective Action Plan (CAP) on October 3, 2011. FCSO denied the CAP on November 1, 2011 because it did not receive the additional information that it requested. CMS Ex. 15.

for hearing, and the case was docketed as C-12-382. The parties filed a joint motion for remand, and I dismissed the case. After the dismissal, First Coast Service Options, Inc. (FCSO), a Medicare contractor, by letter dated June 29, 2012, notified Petitioner that it received correspondence related to the remand, removed the earlier revocation, and reinstated Petitioner effective November 18, 2002. CMS Exhibit (Ex.) 29. On that same day, however, FCSO sent another letter to Petitioner denying its application to enroll in the Medicare program. CMS Ex. 28. That letter explained that it found Petitioner did not meet the enrollment requirements related to: demonstrating the proficiency of its interpreting and supervising physicians and technicians, timely notifying CMS of the employment of a supervising physician within 30 days of the physician's employment, and maintaining a telephone number through directory assistance. CMS Ex. 28, at 2-4. The letter further notified Petitioner of its right to request reconsideration.

By letter dated July 27, 2012, FCSO informed Petitioner that it was revoking its Medicare billing privileges effective August 26, 2012.[2] CMS Ex. 30. The bases for the revocation were: Petitioner's failure to show that its supervising and interpreting physicians demonstrated proficiency pursuant to 42 C.F.R. § 410.33(b)(1) and (b)(2) and FCSO's Local Coverage Determination (LCD) L29330. CMS Ex. 30, at 1-2. FCSO also found that Petitioner did not demonstrate that its technicians had the qualifications to perform the ultrasound tests, CT scans, DEXA scans, mammography, or MRI procedures listed on Petitioner's application in violation of 42 C.F.R. § 410.33(c), (g)(12) and LCD L29330. CMS Ex. 30. FCSO also found that Petitioner did not meet the regulatory requirements at 42 C.F.R. § 410.33(g)(5)(ii) and (g)(8) because it did not have a phone number available through directory assistance and a complete beneficiary complaint resolution form. CMS Ex. 30, at 3. Finally, FCSO explained that Petitioner failed to report within 30 days that it had employed a supervising physician on June 1, 2010, in violation of 42 C.F.R. § 410.33(g)(2). CMS Ex. 30, at 3. Petitioner filed for a reconsideration decision.

By letter dated January 15, 2013, FCSO issued a reconsideration decision affirming Petitioner's revocation from the Medicare program on the bases set forth in FCSO's revocation determination dated July 27, 2012. CMS Ex. 32.

Petitioner filed a request for hearing before an administrative law judge (ALJ). I issued an Acknowledgment and Pre-Hearing Order (Order). Pursuant to that Order, CMS filed

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[2] Considering Petitioner was already enrolled in the Medicare program and was undergoing a revalidation of its enrollment, FCSO should not have issued the notice on June 29, 2012, "denying" Petitioner's enrollment application. However, FCSO properly issued the revocation notice dated July 27, 2012, revoking Petitioner's billing privileges effective August 26, 2012, 30 days from the date of the notice. Petitioner contends that it did not receive the July 27, 2012 revocation notice; however, Petitioner did file a timely request for reconsideration on August 29, 2012, albeit to the June 29, 2012 denial which was based on the same factors. CMS Ex. 31.

its brief (CMS Br.), a motion for summary judgment, and 38 exhibits, CMS Exs. 1-38. Petitioner submitted a motion requesting an extension of time due to power outages closing its attorney's office for five days, together with its pre-hearing exchange memorandum (P. Br.) and six exhibits, P. Exs. I-VI. On June 21, 2013, received in my office on July 11, 2013, Petitioner filed a response in opposition to CMS's motion for summary judgment (P. Response). I admit without objection the parties' exhibits.

My Order specifically directed the parties that, if they proposed witnesses, they must include as an exhibit with their exchange the written direct testimony of any proposed witness. Order ¶¶ 4.c.iv., 8; *see Vandalia Park*, DAB No. 1940 (2004); *Pacific Regency Arvin*, DAB No. 1823, at 8 (2002) (holding that the use of written direct testimony for witnesses is permissible so long as the opposing party has the opportunity to cross-examine those witnesses). I further informed the parties that they must submit witness statements in the form of an affidavit made under oath or as a written declaration that the witness signs under penalty of perjury for false testimony. CMS did not propose any witnesses. Petitioner did not comply with my Order by submitting written direct testimony for proposed witnesses. I find, therefore, that an in-person hearing in this case is unnecessary, and I issue this decision on the full merits of the written record.

II. Applicable Law

Enrollment Requirements

A provider or supplier must be enrolled in the Medicare program and have a billing number in order to be eligible to receive payment for services rendered to a Medicare-eligible beneficiary. 42 C.F.R. § 424.505. "Suppliers," such as Petitioner, include physicians or other practitioners and facilities "other than providers of services."[3] 42 U.S.C. § 1395x(d).

To maintain Medicare billing privileges, a supplier must resubmit and recertify the accuracy of its enrollment information every five years. 42 C.F.R. § 424.515. To revalidate its enrollment, a supplier must submit an enrollment application and meet the requirements outlined at 42 C.F.R. § 424.510. 42 C.F.R. § 424.515(a). The supplier must submit the applicable enrollment application, with complete and accurate information and supporting documentation, within 60 calendar days of the notification to resubmit and certify the accuracy of its enrollment information. *Id.*

[3] "Providers" include hospitals, critical access hospitals, skilled nursing facilities, comprehensive outpatient rehabilitation facilities, home health agencies, and hospice programs. 42 U.S.C. § 1395x(u); 42 C.F.R. § 400.202.

CMS may revoke a supplier's enrollment in the Medicare program if it finds a supplier not to be in compliance with enrollment requirements. 42 C.F.R. § 424.535(a)(1). Except for circumstances not applicable here, the revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the supplier. 42 C.F.R. § 424.535(g). After a supplier's billing privileges are revoked, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the re-enrollment bar. 42 C.F.R. § 424.535(c). The re-enrollment bar is a minimum of 1 year but not greater than 3 years, depending on the severity of the basis for revocation. *Id.*

Certification Requirements for IDTFs

Medicare will pay for diagnostic procedures only when performed by a physician, a group of physicians, an approved supplier of portable x-ray services, a nurse practitioner, a clinical nurse specialist who performs a state-authorized test, or an IDTF. 42 C.F.R. § 410.33(a)(1). The diagnostic procedures that an IDTF may perform are listed at 42 C.F.R. § 410.32. Generally all diagnostic x-ray and other diagnostic tests covered under Medicare, and payable under the physician fee schedule, must be furnished under the appropriate level of supervision by a physician. 42 C.F.R. § 410.32(b). To enroll in the Medicare program, an IDTF must certify in its enrollment application that it meets certain credentialing standards. 42 C.F.R. § 410.33(g). These include enrolling for any diagnostic services that it furnishes to a Medicare beneficiary; having technical staff on duty with appropriate credentials to perform tests; demonstrating that it answers, documents, and maintains documentation of a beneficiary's written clinical complaint at the physical site of the IDTF; and maintaining a primary business phone number, including telephone or toll free telephone numbers available in a local directory and through directory assistance. 42 C.F.R. § 410.33(g)(5), (8), (12), (16).

An IDTF must have one or more supervising physicians who are responsible for: the direct and ongoing oversight of the quality of the testing performed, the proper operation and calibration of equipment used to perform tests, and the qualification of non-physician IDTF personnel who use the equipment. 42 C.F.R. § 410.33(b)(1); Medicare Program Integrity Manual (MPIM), CMS Pub. 100-08, Ch. 15, § 15.5.19.5.[4] The supervising physician must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed at the IDTF—

> The proficiency may be documented by certification in specific medical specialties or subspecialties or by criteria established by the carrier [i.e. Medicare contractor] for the service area in which the IDTF is located.

[4] The MPIM is available on CMS's website at www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html.

42 C.F.R. § 410.33(b)(2). Thus, in its enrollment application, the prospective IDTF must indicate the highest level of physician supervision for the tests that it intends to perform. MPIM, CMS Pub. 100-08, Ch. 15, § 15.5.19.5.C. An IDTF may bill for services provided by physicians who interpret the diagnostic test, but any interpreting physician must be listed on the enrollment application and must be qualified to interpret the types of tests, or codes listed. MPIM, Ch. 15, § 15.5.19.3.

FCSO issued a Local Coverage Determination (LCD), L29330, which further specifies the requirements for IDTFs located within its service area of Florida, Puerto Rico and the Virgin Islands. CMS Ex. 33, at 2. Referencing the regulatory requirement at 42 C.F.R. § 410.33(b)(2), the LCD states that a supervising physician must evidence proficiency in the performance and interpretation of each type of diagnostic procedure the IDTF performs. CMS Ex. 33, at 5. The LCD further provides that supervising physicians must meet the qualification requirements as listed in the credentialing matrix attached to the LCD. That matrix requires that the supervising physician be a Board Certified radiologist certified by the American Board of Medical Specialties (ABMS) for the diagnostic tests that Petitioner indicated in its enrollment application. CMS Ex. 34, at 3-25; CMS Ex. 22 (CPT Codes listed in the enrollment application). Also, the LCD requires that the interpreting physician for a test billed by the IDTF meet the same qualification requirements as the supervising physician of that test. CMS Ex. 34, at 1-2.

Non-physician personnel an IDTF uses to perform tests must demonstrate the basic qualifications to perform the test in question and have training and proficiency, as evidenced by licensure or certification by the appropriate state health or education department. 42 C.F.R. § 410.33(c). In the absence of a state licensing board, an appropriate national credentialing board must certify the technician. *Id.* The IDTF must have technical staff on duty with the appropriate credentials to perform tests and must be able to produce the applicable federal or state licenses of the individuals performing these services. 42 C.F.R. § 410.33(g)(12). FCSO's LCD L29330 and its credentialing matrix list the credentialing requirements for all non-physician personnel with respect to each diagnostic test (codes) that an IDTF may perform and for which it bills Medicare. CMS Exs. 33, 34. Some codes require only that the non-physician technician have a state license as a general radiographer or medical physicist while other codes require credentialing of the technician by an appropriate national organization in a particular specialty or subspecialty.

CMS will revoke an IDTF's billing privileges if the IDTF is found not to comply with application certification standards in paragraph 42 C.F.R. § 410.33(g) or (b)(1). 42 C.F.R. § 410.33(h).

III. Discussion

A. Issue

The sole issue before me is whether CMS had a legitimate basis to revoke Petitioner's Medicare billing privileges.

B. Findings of Fact and Conclusions of Law

1. CMS had a legitimate basis to revoke Petitioner's Medicare billing privileges pursuant to 42 C.F.R. § 410.33(h) and 42 C.F.R. § 424.535(a)(1) because Petitioner was not in compliance with Medicare requirements for an IDTF located in Puerto Rico.[5]

a. Petitioner did not show that its supervising and interpreting physicians met Medicare qualification requirements.

Enrollment requirements for IDTFs require that an IDTF have one or more supervising physicians who are limited to providing general supervision at no more than three IDTF sites. 42 C.F.R. § 410.33(b)(1). The supervising physician is responsible for the direct and ongoing oversight of the quality of the testing performed, the proper calibration and operation of the equipment used to perform tests, and the qualification of non-physician IDTF personnel who use the equipment. MPIM, Ch. 15, § 15.5.19.5. The supervising physician must evidence proficiency in "the performance and interpretation of each type of diagnostic procedure performed by the IDTF." 42 C.F.R. § 410.33(b)(2). The proficiency is required to be "documented by certification in specific medical specialties or subspecialties or by criteria established by the carrier for the service area in which the IDTF is located." *Id.* The carrier, FCSO, established an LCD, L29330, in effect since March 2, 2009, which requires that the supervising physician be a Board Certified radiologist as certified by the American Board of Medical Specialties (ABMS). CMS Ex. 34. That LCD also requires that the interpreting physician for a test billed by the IDTF meet the same qualification requirements as the supervising physician, and the interpreting physician must be qualified to interpret the types of tests or codes listed. *Id.*

Medicare contractors may determine the proficiency that must be established for the performance and interpretation of each type of diagnostic procedure performed. 42 C.F.R. § 410.33(b)(2). In this instance, under LCD 29330, FSCO set forth a credentialing matrix for supervising and interpreting physicians of tests billed by the

[5] The applicable regulations provide that that failure to meet even one application certification standard or noncompliance with at least one enrollment requirement is sufficient as a basis for revocation. Therefore, I will only address FSCO's most significant findings of noncompliance with the regulations and standards.

IDTF. The matrix states that for the CPT codes listed (here codes 70030-76101 and 76529-76970), both the supervising and interpreting physician qualification requirements are for a "Board Certified (ABMS) Radiologist." CMS Exs. 34, at 3-16; 8; 14; 22.

Petitioner does not dispute that the two physicians listed in its enrollment application as both supervising and interpreting physicians were not Board Certified by the ABMS. Petitioner contends, however, that its physicians' credentials were issued by the Department of Health of the Commonwealth of Puerto Rico. P. Response at 13. Petitioner claims that the Junta de Licencimiento y Disciplina Medica, Departamento de Salud (Board of Medicine License and Discipline), is a "member of the *Federal State Medical Board* and as such is in compliance with state and federal law." P. Response at 13. The licenses for both physicians state they are licensed to practice medicine and surgery in Puerto Rico and that they hold a specialty or subspecialty certificate in Diagnostic Radiology. P. Ex. VI.

Considering neither of Petitioner's supervising and interpreting physicians met the required criteria for ABMS Board Certification in Radiology, they cannot properly be considered supervising or interpreting physicians under the regulatory and LCD criteria. The criteria here are very specific and FCSO determined in its LCD credentialing matrix that state or local certification in a specialty or subspecialty was insufficient and that only national certification as a Board Certified Radiologist by ABMS would satisfy the qualification requirements for IDTF supervising and interpreting physicians. I therefore find that Petitioner did not meet the required certification standards for supervising and interpreting physicians under 42 C.F.R. § 410.33(b)(1) and therefore CMS had a basis for revocation. *See* 42 C.F.R. §§ 410.33(h), 424.535(a)(1).

b. Petitioner did not show that its non-physician technicians had the appropriate credentials to perform certain tests for which they were seeking approval.

In order to meet the regulatory standards for an IDTF, the IDTF must show that its technical staff have the appropriate credentials to perform the tests, and the IDTF must be able to produce the applicable federal or state licenses or certifications of the individuals performing these services. 42 C.F.R. § 410.33(c), (g)(12). Also, non-physician personnel the IDTF uses to perform tests must demonstrate the basic qualifications for training and proficiency as evidenced by the appropriate state health or education department. In the absence of a state licensing board, the non-physician personnel must be certified by an appropriate national credentialing body. 42 C.F.R. § 410.33(c). Further, FCSO's LCD L29330 and its credentialing matrix list credentialing requirements for all non-physician personnel with respect to each diagnostic test that an IDTF may perform and for which it bills Medicare. CMS Exs. 33; 34.

The three technicians that Petitioner identifies in its enrollment application did not have qualifications to perform certain procedures Petitioner listed it would perform on its revalidation application. The technologists all had Puerto Rican licenses as radiology technicians. CMS. Ex. 8, at 50-55. Under the provisions of LCD L29330 certain tests may only be conducted by technicians credentialed by an appropriate national organization in a particular specialty or subspecialty. The specific credentialing organization is listed in the LCD next to the specific CPT/HCPCS codes for those tests. Those organizations are the American Registry of Radiologic Technologists (ARRT), American Registry of Diagnostic Medical Sonographers (ARDMS), or American Registry of Resonance Imaging Technologists (ARMRIT). CMS Ex. 33, at 6; CMS Ex. 34. For example, for CPT codes 70542 and 70543, the technician qualifications require credentialing by "AART for MR or by ARMRIT for MRI." CMS Ex. 34, at 5. Other codes such as CPT 76814 - 76970 require credentialing only by ARDMS or ARRT. CMS Ex. 22, at 2, 13-18; CMS Ex. 34. For these tests, Puerto Rican licensure is insufficient without the national accreditation. I find therefore that Petitioner did not show that its three technicians were qualified to perform many of the tests that it listed in its application, and therefore FSCO had another legitimate basis for revocation of Petitioner's enrollment and billing privileges pursuant to 42 C.F.R. § 410.33 (g)(12) and 42 C.F.R. § 410.33(h).

c. Petitioner failed to meet Medicare requirements related to changes in general supervision because it did not timely submit a change of information form for one of its supervisory physicians.

Any changes in general supervision for an IDTF must be reported to the Medicare contractor on a Medicare enrollment application within 30 calendar days of the change. 42 C.F.R. § 410.33(g)(2). Here, Petitioner first notified FCSO that it was using Dr. Bonnet as a supervising physician when it submitted a change of information form (CMS 855B) to FCSO on August 22, 2011. CMS Ex. 6. Then Petitioner's revalidation application, submitted to FSCO on October 13, 2012, sought to add Dr. Bonnet as a supervising physician providing general supervision effective June 1, 2010. CMS Ex. 14, at 104. Thus, it appears Petitioner failed to properly inform FCSO in 2010 that Dr. Bonnet was acting as a supervising physician within 30 days of the change as required by the applicable regulation. Petitioner did not specifically contest this allegation. Therefore, Petitioner failed to provide FCSO with complete and accurate information and any changes to that information within the required 30 calendar days of the change. Accordingly, Petitioner's failure to report this information as required by 42 C.F.R. 410.33(g)(2) is considered a failure to meet the application certification standards and is a legitimate basis under 42 C.F.R. § 410.33(h) for revoking Petitioner's billing privileges.

IV. Conclusion

I find that Petitioner did not meet the standards and requirements applicable to an IDTF because its employees did not have the proper qualifications, and it did not properly notify CMS of a change with its supervisory physician. Therefore, I affirm CMS's determination to revoke Petitioner's Medicare enrollment and billing privileges and to impose a one-year re-enrollment bar. I further find that the revocation became effective August 26, 2012, 30 days after the FCSO notified Petitioner by letter dated July 27, 2012 of the revocation.

/s/
Joseph Grow
Administrative Law Judge