Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Centro Radiologico Rolon, Inc.
Docket No. A-14-59
Decision No. 2579
June 27, 2014

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Centro Radiologico Rolon, Inc. (Petitioner), a Puerto Rico corporation, appeals a decision by an Administrative Law Judge (ALJ) which sustained the revocation of its Medicare enrollment by the Centers for Medicare & Medicaid Services (CMS). *Centro Radiologico Rolon, Inc.*, DAB CR3136 (2014) (ALJ Decision). Although Petitioner asserts that CMS improperly revoked its enrollment, Petitioner has not shown that the ALJ's decision is based on legal errors or on factual findings not supported by substantial evidence. We therefore affirm the ALJ Decision.

Legal Background

Petitioner was enrolled in the Medicare program as an independent diagnostic testing facility (IDTF). An IDTF is an entity (other than a physician's office or hospital) that provides diagnostic imaging services, such as x-rays, computed tomography (CT), magnetic resonance imaging (MRI), and ultrasonography. With a few exceptions, Medicare pays for a diagnostic test only if it is performed under at least a "general" level of supervision. *See* 42 C.F.R. § 410.32(b). In light of that payment limitation, CMS requires that an IDTF "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 the equipment used to perform tests, and the qualification of nonphysician personnel who use the equipment."[1] 62 Fed. Reg. 59,048, 59,071 (Oct. 31, 1997) (italics added).

[1] The quoted passage was originally included in the text of 42 C.F.R. § 410.33(b)(1) but replaced with different language in 2006. 62 Fed. Reg. at 59,099; 71 Fed. Reg. 69,624, 69,784 (Dec. 1, 2006) (amending paragraph (b)(1) to hold a supervising physician "responsible for the overall operation and administration" of an IDTF). The replacement language was deleted in 2007, but the original language (stating that supervising physicians are "responsible for the direct and ongoing oversight of the quality of the testing performed") was not restored. 72 Fed. Reg. 62,222, 66,287-88, 66,398 (Nov. 27, 2007). However, the original language has been retained by CMS in policy guidance and program manuals, and it is consistent with the regulatory definition of "general supervision" in 42 C.F.R. § 410.32(b)(3). *See, e.g.*, Medicare Program Integrity Manual, CMS Pub. 100-08, § 15.5.19.5(A), available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019033.

In order to become enrolled and maintain enrollment in (and thus be eligible to receive payment from) the Medicare program, an IDTF must be in compliance with the requirements in 42 C.F.R. § 410.33. At issue here are paragraphs (b)(2) and (g) of section 410.33. Paragraph (b)(2) requires an IDTF to document the proficiency of its supervising physicians in performing and interpreting each type of diagnostic procedure being performed in its facility. Paragraph (g) states that an IDTF must certify (on a Medicare enrollment application) its compliance with 17 standards. One of those standards, set forth in paragraph (g)(12), requires an IDTF's non-physician "technical staff" to have "appropriate credentials" to perform tests. Another standard, set forth in paragraph (g)(2), requires an IDTF to report to CMS, within specified timeframes, certain changes to previously provided enrollment information, including "changes in general supervision."

CMS's legal authority to revoke an IDTF's Medicare enrollment is found in two places. First, paragraph (h) of section 410.33 states that "CMS will revoke a supplier's billing privileges if an IDTF is found not to meet the standards in paragraph (g) or (b)(1) of this section." (Paragraph (b)(1) of section 410.33 states that "each supervising physician must be limited to providing general supervision to no more than three IDTF sites.") Second, 42 C.F.R. § 424.535(a) authorizes CMS to revoke a provider's or supplier's enrollment for any of the "reasons" enumerated in that section, including (as stated in paragraph (a)(1)) noncompliance with the "enrollment requirements described . . . in the enrollment applicable for its provider or supplier type . . . ."

Case Background

This case has a somewhat convoluted history, which the ALJ accurately described. We reiterate only the circumstances relevant to our review.

On July 27, 2012, a CMS contractor (from this point, we use the acronym CMS to refer to both CMS and its contractor, unless there is a need to distinguish them) notified Petitioner that its "billing privileges" had been revoked effective August 26, 2012. [2] CMS Ex. 30. CMS alleged multiple grounds for its determination, *id.* at 1-4, but we mention only the three grounds addressed in the ALJ Decision. First, CMS alleged that Petitioner was noncompliant with section 410.33(b)(2) because its supervising physicians, though licensed to practice medicine in the Commonwealth of Puerto Rico, lacked certification in radiology from the American Board of Medical Specialties (ABMS). Second, CMS alleged that Petitioner was noncompliant with section 410.33(g)(12) because its non-physician technicians lacked appropriate credentials to

[2] The revocation determination is entwined chronologically with CMS's rejection of Petitioner's attempt to "revalidate" its Medicare enrollment pursuant to 42 C.F.R. § 424.515. *See* ALJ Decision at 2 & n.2.

perform some of its diagnostic procedures (such as CT and MRI). Third, CMS alleged that Petitioner had violated section 410.33(g)(2) by failing to report a change in general supervision within 30 days of the change.

Petitioner asked CMS to reconsider its initial determination, but a CMS hearing officer upheld the revocation on the same grounds. CMS Ex. 32. Petitioner then requested a hearing before the ALJ.

CMS moved for summary judgment in response to Petitioner's hearing request, contending that undisputed facts substantiated the alleged grounds for revocation and that each ground was legally sufficient to sustain the revocation. Petitioner filed a brief opposing CMS's motion. *See* June 21, 2013 Response in Opposition to Motion for Summary Judgment. That brief asserted that there were "material controversies as to the facts presented by" CMS, *id.* at 11, but did not clearly specify which of the facts alleged by CMS were in dispute. Furthermore, in its pre-hearing exchange memorandum, Petitioner indicated that there were no "contested material facts." June 17, 2013 Pre-Hearing Exch. Mem. at 8. Petitioner's pre-hearing exchange memorandum identified four witnesses for a hearing but did not state that their testimony would bear upon any identified factual disputes. The ALJ had earlier instructed the parties to submit the written direct testimony of any proposed witness as part of their pre-hearing exchange. *See* Mar. 21, 2013 Acknowledgment and Pre-Hearing Order at 5. However, Petitioner did not submit written direct testimony of any of its four proposed witnesses.

Because Petitioner failed to submit its proposed witnesses' written direct testimony, the ALJ ruled that an in-person hearing was unnecessary and issued his decision "on the full merits of the written record." ALJ Decision at 3. Based on that record,[3] the ALJ found that Petitioner: (1) failed to comply with section 410.33(b)(2) because its supervising physicians were not "board certified" by the ABMS; (2) failed to comply with section 410.33(g)(12) because its technicians lacked appropriate credentials to perform certain diagnostic procedures being furnished in its facility; and (3) violated section 410.33(g)(2) by not timely notifying CMS when one of its supervising physicians began to provide general supervision in its facility. *Id.* at 6-8. The ALJ concluded that these violations authorized CMS to revoke Petitioner's enrollment under section 410.33(h) or section 424.535(a)(1).

Petitioner then filed this appeal, contending that it is compliant with all Medicare requirements to be enrolled in Medicare as an IDTF and urging the Board to reverse the ALJ Decision. Petitioner's Appeal Brief (P. Br.) at 17.

[3] That record consists of documentary evidence submitted as part of the parties' pre-hearing exchange plus material submitted in support of, or opposition to, CMS's summary judgment motion.

Discussion

We note initially that the ALJ effectively denied CMS's summary judgment motion by proceeding to decide the case on the written record due to Petitioner's failure to timely comply with his pre-hearing order. Petitioner does not allege that there are genuine disputes of material fact that warrant an in-person hearing, that it was unfairly denied an opportunity to present evidence, or that the ALJ committed a prejudicial error by not applying a summary judgment standard to decide the case. Accordingly, we review the ALJ Decision under the appellate standard applicable to ALJ decisions issued after a full opportunity for a hearing. Under that standard, the Board reviews a disputed finding of fact to determine whether it is supported by substantial evidence on the record as a whole. *Guidelines — Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs*, http://www.hhs.gov/ dab/divisions/appellate/ guidelines/prov.html. The Board's standard of review concerning a disputed conclusion of law is whether the conclusion is erroneous. *Id.*

We now turn to the three regulatory violations found by the ALJ.

1. *The ALJ's conclusion that Petitioner was noncompliant with 42 C.F.R. § 410.33(b)(2) is supported by substantial evidence and free of legal error.*

Section 410.33(b)(2) states that an IDTF's supervising physicians "must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF." That regulation further states that the physician's "proficiency" may be "documented" by showing that the physician has "certification in specific medical specialties or subspecialties" or by demonstrating that the physician meets "criteria established by the carrier for the service area in which the IDTF is located."

The ALJ found that the Medicare "carrier" (that is, the CMS Medicare Part B contractor) for Petitioner's service area has established criteria – published in local coverage determination (LCD) L29330 and an associated "credentialing matrix" – for documenting the proficiency required by section 410.33(b)(2). ALJ Decision at 5, 6-7. With respect to the procedures that Petitioner claimed to be performing (as indicated on its enrollment application), the ALJ found that the carrier's proficiency criteria required Petitioner's supervising physicians to be "board certified" in radiology by an ABMS member organization.[4] *Id.* The ALJ also found that Petitioner's supervising physicians do not hold ABMS certifications in radiology. *Id.* at 7. Based on these findings, the ALJ concluded that Petitioner was not in compliance with section 410.33(b)(2). *Id.*

[4] ABMS's member boards include the American Board of Radiology. *See* http://www.abms.org/about abms/member_boards.aspx.

Petitioner does not dispute the ALJ's findings that its Medicare carrier has established proficiency criteria for supervising physicians in IDTFs, that those criteria were in effect when CMS revoked its enrollment, that the criteria required its supervising physicians to be board certified in radiology by the ABMS, or that its supervising physicians lack such certification. *See* P. Br. at 15-18. Furthermore, Petitioner does not contend that the ALJ committed legal error in using the carrier's criteria to assess its compliance with section 410.33(b)(2). *Id.*

Instead, Petitioner merely alludes to the "License Verifications" issued by the Puerto Rico medical licensing board for the two physicians in question. CMS Ex. 24, at 9, 12; P. Br. at 16. In addition to stating that the physicians are authorized to practice medicine in the Commonwealth of Puerto Rico, the License Verifications indicate that the physicians hold "specialty certificates" in diagnostic radiology issued by the licensing board. CMS Ex. 8, at 9, 12; CMS Ex. 24, at 8, 11 (identifying the issuer of the specialty certificates as the Tribunal Examinador de Medicos de Puerto Rico (Puerto Rico Board of Medical Examiners), now known as the Puerto Rico Board of Licensing and Medical Disciplines[5]). However, Petitioner did not submit evidence of the skills, training, experience, and testing necessary to obtain the specialty certificates. At no point during the administrative review process has Petitioner explained why those certificates should be regarded as sufficient evidence of its supervising physicians' proficiency in the performance and interpretation of "each type of diagnostic procedure performed" in its facility.[6] Nor has Petitioner established that the specialty certificates are somehow functionally equivalent to ABMS board certification. Petitioner's appeal brief is completely silent about the significance of the supervising physicians' specialty certificates.

In short, Petitioner has failed to demonstrate that the ALJ's findings on this issue are not supported by substantial evidence or are based on errors of law. We therefore affirm his conclusion that Petitioner was not compliant with section 410.33(b)(2).[7]

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[5] *See* 2008 P.R. Laws 139 (Aug. 1, 2008), available at http://www.oslpr.org/2005-2008/leyes/pdf/ley-139-01-Ago-2008.pdf.

[6] Because Petitioner did not present any evidence or argument about its specialty certificates or contend that the ALJ erred in relying on the carrier's proficiency criteria, we need not decide whether (or under what circumstances) certification by a non-ABMS entity – such as a state medical licensing board or another non-governmental credentialing organization – may constitute sufficient evidence of compliance with section 410.33(b)(2).

[7] In concluding that Petitioner was noncompliant with the proficiency requirements applicable to its supervising physicians, the ALJ mistakenly cited paragraph (b)(1), rather than paragraph (b)(2), as the source of those requirements. *See* ALJ Decision at 7 (final sentence of section II.B.1.a.).

2. *The ALJ's conclusion that Petitioner was noncompliant with 42 C.F.R. § 410.33(g)(12) is supported by substantial evidence and free of legal error.*

Section 410.33(g)(12) states that an IDTF must "[h]ave technical staff on duty with the *appropriate credentials* to perform tests" (italics added) and "must be able to produce the applicable Federal or State licenses or certifications of the individuals performing these services." What constitutes "appropriate credentials" is explained to some degree in section 410.33(c). That regulation states that "nonphysician personnel used by the IDTF to perform tests must demonstrate the *basic qualifications* to perform the tests in question and have *training and proficiency as evidenced by licensure or certification* by the appropriate State health or education department" (italics added). Section 410.33(c) further states that "[i]n the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body."

In assessing Petitioner's compliance with section 410.33(g)(12), the ALJ looked again to the carrier's LCD (L29330) and credentialing matrix. He found that the LCD and matrix specify "credentialing requirements for all non-physician personnel with respect to each diagnostic test that an IDTF may perform and for which it bills Medicare." ALJ Decision at 7. The ALJ also found that for some types of diagnostic procedures – such as CT, MRI, and ultrasonography – the LCD and matrix call for a technician to possess specialty or sub-specialty credentials issued by "an appropriate national organization," such as the American Registry of Radiologic Technologists (ARRT), the American Registry of Resonance Imaging Technologists (ARMRIT), or the American Registry of Diagnostic Medical Sonographers (ARDMS). *Id.* at 8.

Petitioner does not dispute that its technicians lack the credentials specified by the carrier for CT, MRI, and ultrasonography, nor does Petitioner deny that those diagnostic procedures are performed in its facility. Instead, Petitioner points to evidence that the technicians are licensed by the Puerto Rico Department of Health as radiology technologists. *See* CMS Ex. 8, at 50-55; P. Br. at 17. However, section 410.33(g)(12) plainly requires Petitioner's technicians to have "appropriate credentials" to perform CT, MRI, and ultrasonography, and Petitioner does not allege – and submitted no evidence – that the technicians' Puerto Rico licenses reflect adequate "training and proficiency" to perform those diagnostic procedures. For that reason, we affirm the ALJ's conclusion that Petitioner was not compliant with section 410.33(g)(12).

3. *Petitioner violated 42 C.F.R. § 410.33(g)(2) when it failed to advise CMS of a change in general supervision within 30 days of the change.*

The ALJ found that in August 2011, Petitioner submitted to CMS a change-of-information form indicating that a physician named Dr. Bonnet was providing "general supervision" at its facility. ALJ Decision at 8. The ALJ also found that the "effective date" of that change, as noted in a later-filed "revalidation" application, was

June 1, 2010. *Id.* Petitioner does not dispute these findings of fact, and we agree with the ALJ that the undisputed facts show a violation of section 410.33(g)(2). That regulation requires an IDTF to report "changes in general supervision . . . to the Medicare fee-for-service contractor . . . within 30 days of the change." As the ALJ concluded, Petitioner violated section 410.33(g)(2) because it did not report the June 2010 change in general supervision involving Dr. Bonnet for more than one year.

4. *Each regulatory violation found by the ALJ was a legally sufficient basis for revocation.*

Based on Petitioner's violations of sections 410.33(b)(2), 410.33(g)(12), and 410.33(g)(2), the ALJ concluded that the regulatory elements necessary for CMS to exercise its revocation authority under sections 410.33(h) and 424.535(a)(1) were present. *See* ALJ Decision at 6, 7. Petitioner does not challenge that conclusion, and thus we summarily affirm it. We also point out that each of Petitioner's violations independently constitute a sufficient basis upon which to sustain the revocation. *Cf. 1866ICPayday.com, L.L.C.*, DAB No. 2289, at 13 (2009) (affirming the revocation of a DMEPOS supplier under 42 C.F.R. § 424.57(d), which authorizes revocation if the supplier "is found not to meet the standards in paragraphs (b) and (c)," and holding that "failure to comply with even one supplier standard is a sufficient basis for revoking a supplier's billing privileges").

Conclusion

For the reasons stated above, we affirm the ALJ's conclusion that CMS lawfully revoked Petitioner's Medicare enrollment under 42 C.F.R. §§ 410.33(h) and 424.535(a)(1).

/s/
Leslie A. Sussan

/s/
Constance B. Tobias

/s/
Stephen M. Godek
Presiding Board Member