Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Liberty Laboratory, Inc.,
(CLIA No.: 15D1019268),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-13-237

Decision No. CR2995

Date: November 14, 2013

DECISION

The certificate to operate as a clinical laboratory under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) of Petitioner, Liberty Laboratory, Inc., is revoked effective the date of this decision. 42 C.F.R. § 493.1844(d)(4)(ii). The owners and operators of Petitioner are prohibited from owning, operating, or directing a laboratory for two years pursuant to 42 U.S.C. § 263a(i)(3) due to the revocation of Petitioner's CLIA certificate. The two-year prohibition runs from the date of the revocation of the laboratory's certificate, i.e., the date of this decision, pursuant to 42 U.S.C. § 263a(i)(3).

I. Background

Petitioner is a clinical laboratory located in Tell City, Indiana. Petitioner had a CLIA certificate to perform nonwaived, moderate complexity testing. The Indiana State Department of Health (state agency) conducted a complaint survey of Petitioner's facility on August 22 and 23, 2012. The state agency found that Petitioner was not in compliance with the following three regulatory conditions for Medicare coverage of its services:

42 C.F.R. §§ 493.803;[*] 493.1250; and 493.1403. The Centers for Medicare & Medicaid Services (CMS) notified Petitioner by letter dated October 16, 2012, that CMS was imposing the following enforcement remedies: suspension of Petitioner's CLIA certificate effective October 16, 2012, which was to continue until Petitioner corrected the condition-level deficiencies or its CLIA certificate was revoked; revocation of Petitioner's CLIA certificate effective November 5, 2012, unless a hearing was requested, in which case the revocation would not be effective until upheld after hearing; cancellation of approval to receive payments from Medicare for services performed after October 16, 2012; a directed plan of correction effective October 16, 2012; and a CMP of $1,000 per day for each day of noncompliance. Joint Stipulation of Undisputed Facts (Jt. Stip.); CMS Exhibit (CMS Ex.) 17.

Petitioner requested a hearing before an administrative law judge (ALJ) by an undated letter received at the Civil Remedies Division on December 18, 2012. The parties stipulated that Petitioner's request for hearing was timely filed. Jt. Stip. ¶ 11. The case was assigned to me for hearing and decision on December 26, 2012, and an Acknowledgment and Prehearing Order (Prehearing Order) was issued at my direction.

CMS filed a motion for summary judgment (CMS Br.), with CMS Exs. 1 through 20, on June 20, 2013. Petitioner filed a document on July 19, 2013, entitled "Liberty Laboratory, Inc. Pre-Hearing Brief." The document filed by Petitioner is treated as both Petitioner's response to the CMS motion for summary judgment and as Petitioner's prehearing brief (P. Br.). Petitioner filed no exhibits with its brief. Petitioner does not object to my consideration of CMS Exs. 1 through 20 and they are admitted and considered as evidence. On July 10, 2013, I ordered that further proceedings be stayed pending my resolution of the CMS motion for summary judgment. Summary judgment is granted.

II. Discussion

A. Statutory and Regulatory Program Requirements

CLIA establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens and provides for federal certification of such laboratories. Pub. L. No. 100-578, amending sec. 353 of the Public Health Service Act, codified at 42 U.S.C. § 263a et. seq. The purpose of CLIA is to ensure the accuracy and reliability of laboratory tests, and hence the public health of all Americans. See H.R. Rep. No. 899,

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[*] References are to the 2011 revision of the Code of Federal Regulations (C.F.R.), unless otherwise indicated.

100th Cong. 2d Sess. 8, 18 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3839. CMS certification of a laboratory under CLIA is dependent upon whether the laboratory meets the conditions for certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1)(E); 42 C.F.R. pt. 493. Pursuant to CLIA the Secretary of Health and Human Services (the Secretary) has broad enforcement authority, including the ability to suspend, limit, or revoke the certificate of a laboratory that is out of compliance with one or more requirements for certification.

The Secretary has exercised the authority granted by 42 U.S.C. § 263a(f) and issued regulations implementing CLIA that are codified at 42 C.F.R. pt. 493. The regulations specify conditions and standards for certification that a laboratory must meet and maintain in order to be certified to test human specimens and to participate in Medicare. The regulations confer broad authority on CMS to ensure that laboratories perform as Congress intended, including the authority to inspect and sanction laboratories that fail to comply with the regulatory requirements. CMS has the delegated authority to suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more CLIA conditions, and may also impose alternative sanctions, such as a directed plan of correction, monitoring by the state, and a CMP. 42 C.F.R. § 493.1806-.1844. Under the regulations, a single condition-level violation is an adequate basis for principal and alternative sanctions.

The regulations provide as a condition for participation that a laboratory conducting moderate or high complexity testing, as was Petitioner, must enroll in an approved proficiency testing (PT) program or programs that cover all the specialties and subspecialties for which the laboratory seeks certification. The laboratory is required to test PT samples in the same manner as its regular patients' specimens. 42 C.F.R. § 493.801. It is a condition-level requirement that a laboratory must successfully participate in a PT program approved by CMS for each specialty, subspecialty, and analyte or test for which the laboratory is certified under CLIA. CMS may impose authorized sanctions if a laboratory fails to participate successfully. 42 C.F.R. § 493.803. Unsuccessful PT performance is defined as the "failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two of three consecutive testing events. 42 C.F.R. § 493.2. Generally, a PT score of less than 80 percent is an unsatisfactory score. Failure to participate in a testing event results in a score of 0 for that event. 42 C.F.R. §§ 493.823, .825, .827, .829, .831, .835, .837, .841, .843, .845, .851, .861, and .865. A PT score of less than 100 percent is unsatisfactory for compatibility testing and ABO group and D (Rho) typing. 42 C.F.R. §§ 493.859 and .863.

CMS must cancel a laboratory's approval to receive Medicare payments when CMS suspends or revokes the laboratory's CLIA certificate. 42 C.P.R. § 493.1842(a). CLIA provides at 42 U.S.C. § 263a(i)(1) that a laboratory's certificate may be suspended, revoked, or limited only after reasonable notice and opportunity for hearing to "the owner

or operator of the laboratory . . . ." The Secretary's regulations provide that a laboratory or prospective laboratory dissatisfied with an initial determination listed in 42 C.F.R. § 493.1844(b) is entitled to a hearing before an ALJ. 42 C.F.R. § 493.1844(a). The hearing procedures of 42 C.F.R. subpt. D are applicable pursuant to 42 C.F.R. § 493.1844(a)(2). The "suspension, limitation or revocation of the laboratory's CLIA certificate . . . because of noncompliance . . . ." is an initial determination subject to hearing before an ALJ. 42 C.F.R. § 493.1844(b)(1). The imposition of an alternative sanction, such as a CMP, is also an initial determination that triggers a right to request a hearing. 42 C.F.R. § 493.1844(b)(3). The CMS choice of alternative sanctions to impose, including the amount of a CMP to impose per day or per violation, and the determination that a laboratory's deficiencies pose immediate jeopardy, are not subject to ALJ review. 42 C.F.R. § 493.1844(c)(4), (6) and (7).

Generally when a hearing is requested, revocation of a CLIA certificate is not effective until after a hearing decision is issued by the ALJ. 42 C.F.R. § 493.1844(d)(2).

B. Issues

Whether summary judgment is appropriate; and

Whether there is a basis for the revocation of Petitioner's CLIA certificate.

C. Findings of Fact, Conclusions of Law, and Analysis

My conclusions of law are set forth in bold text followed by my findings of fact, and analysis.

1. Summary judgment is appropriate.

A clinical laboratory subject to a principal or alternative sanction has a right to a hearing and judicial review pursuant to 42 U.S.C. §§ 263a(i) and (k); 42 C.F.R. § 493.1844. A hearing conducted pursuant to 42 C.F.R. pt. 498 is generally a hearing on the record, also known as an oral hearing. *Crestview Parke Care Ctr. v. Thompson*, 373 F.3d 743, 748-51 (6th Cir. 2004). A party may waive appearance at an oral hearing, but must do so affirmatively in writing. 42 C.F.R. § 498.66. In this case, Petitioner has not waived the right to oral hearing or otherwise consented to a decision based only upon the documentary evidence or pleadings. Accordingly, disposition on the written record alone is not permissible, unless the CMS motion for summary judgment has merit.

Summary judgment is not automatic upon request but is limited to certain specific conditions. The procedures established by 42 C.F.R. pt. 498 do not include a summary judgment procedure. However, appellate panels of the Board have long recognized the availability of summary judgment in cases subject to 42 C.F.R. pt. 498, and the Board's

interpretative rule has been recognized by the federal courts. *See, e.g., Crestview,* 373 F.3d at 749-50. Furthermore, a summary judgment procedure was adopted as a matter of judicial economy within my authority to regulate the course of proceedings and made available to the parties in the litigation of this case by my Prehearing Order § II.D.3.

Summary judgment is appropriate, and no hearing is required, where either: there are no disputed issues of material fact and the only questions that must be decided involve application of law to the undisputed facts; or, the moving party must prevail as a matter of law even if all disputed facts are resolved in favor of the party against whom the motion is made. The Board follows the general approach of the federal courts in evaluating whether or not summary judgment in lieu of a hearing is appropriate. The movant bears the initial burden of demonstrating that there are no genuine issues of material fact for trial and that the movant is entitled to judgment as a matter of law. When confronted with a properly supported motion for summary judgment, the nonmoving party "may not rest upon the mere allegations or denials of his pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986) (quoting *First Nat'l Bank of Az. v. Cities Serv. Co*., 391 U.S. 253, 249 (1968)); *see also* Fed. R. Civ. P. 56(c); *Venetian Gardens,* DAB No. 2286, at 10-11 (2009); *Ill. Knights Templar Home,* DAB No. 2274, at 3-4 (2009); *Garden City Med. Clinic*, DAB No. 1763 (2001); *Everett Rehab. & Med. Ctr.*, DAB No. 1628, at 3 (1997) (in-person hearing required where nonmovant shows there are material facts in dispute that require testimony); *Big Bend Hosp. Corp., d/b/a Big Bend Hosp. Ctr.*, DAB No. 1814, at 13 (2002) (in some cases, any factual issue is resolved on the face of the written record because the proffered testimony, even if accepted as true, would not make a difference).

In opposing a motion for summary judgment, the nonmovant bears the burden of showing that there are material facts that are disputed either affecting the movant's prima facie case or that might establish a defense. It is insufficient for the nonmovant to rely upon mere allegations or denials to defeat the motion and proceed to hearing. The nonmovant must, by affidavits or other evidence that sets forth specific facts, show that there is a genuine issue for trial. If the nonmovant cannot show by some credible evidence that there exists some genuine issue for trial, then summary judgment is appropriate and the movant prevails as a matter of law. *Anderson*, 477 U.S. at 247. A test for whether an issue is regarded as genuine is if "the evidence [as to that issue] is such that a reasonable jury could return a verdict for the nonmoving party." *Id*. at 248. In evaluating whether there is a genuine issue as to a material fact, an ALJ must view the facts and the inferences to be drawn from the facts in the light most favorable to the nonmoving party. *Pollock v. Am. Tel. & Tel. Long Lines,* 794 F.2d 860, 864 (3rd Cir. 1986).

The standard for deciding a case on summary judgment, and an ALJ's decision-making in deciding a summary judgment motion, differs from resolving a case after a hearing. On summary judgment, the ALJ does not make credibility determinations, weigh the

evidence, or decide which inferences to draw from the evidence, as would be done when finding facts after a hearing on the record. Rather, on summary judgment the ALJ construes the evidence in a light most favorable to the non-movant and avoids deciding which version of the facts is more likely true. *Holy Cross Vill. at Notre Dame, Inc*, DAB No. 2291, at 5 (2009). The Board also has recognized that on summary judgment it is appropriate for the ALJ to consider whether a rational trier of fact could find that a party's evidence, i.e., the movant's evidence, would be sufficient to meet that party's evidentiary burden. *Dumas Nursing & Rehab., L.P.*, DAB No. 2347, at 5 (2010); *Ill. Knights Templar Home*, DAB No. 2274, at 8.

In deciding that summary judgment is appropriate in this case, I note that Petitioner offered no affidavit or declaration in support of its response to CMS's motion for summary judgment. Further, as discussed hereafter, it is not disputed that Petitioner failed to successfully participate in a PT program approved by CMS. The undisputed fact that Petitioner failed to successfully participate in a PT program is, as a matter of law, a condition-level violation and a basis for revocation of Petitioner's CLIA certificate and the imposition of a CMP. There is no genuine dispute as to the material fact that Petitioner did not satisfactorily participate in a CMS approved PT program. Petitioner's arguments and allegations of fact do not rebut the CMS prima facie case; raise a genuine dispute of material fact as to a defense; and must be resolved against Petitioner on the law. Accordingly, there is no need for a hearing to receive evidence and summary judgment is appropriate.

2. Petitioner violated the condition-level requirement of 42 C.F.R. § 493.803, which requires successful participation in proficiency testing.

3. There is a basis for revocation of Petitioner's CLIA certificate.

The CMS letter dated September 6, 2012, which notified Petitioner of the CMS proposal to implement sanctions, and the CMS letter dated October 16, 2012, which notified Petitioner that sanctions were imposed, cite violations of 42 C.F.R. §§ 493.803, 493.1250, and 493.1403 as the basis for imposition of sanctions. CMS Exs. 1 and 17. CMS alleges that summary judgment is appropriate as to the alleged violation of 42 C.F.R. § 493.803, and that the condition-level deficiency at 42 C.F.R. § 493.803 is an adequate basis for revocation of Petitioner's CLIA certificate. The CMP referenced in the CMS notices is not at issue, as no CMP accrued in this case because suspension of Petitioner's CLIA certificate occurred on October 16, 2012, the date on which the CMP was to begin accruing. CMS Br. at 3 n. 2. A single, condition-level violation is a sufficient basis for revocation of Petitioner's CLIA certificate. Further, CMS is correct that summary judgment is appropriate as to the violation of 42 C.F.R. § 493.803. Accordingly, it is not necessary to consider the additional alleged deficiencies, and only the violation of 42 C.F.R. § 493.803 is analyzed in this decision.

The surveyors allege in the statement of deficiencies (SOD) for the survey completed on August 23, 2012, that Petitioner failed to successfully participate in an approved PT program in violation of the condition-level requirement established by 42 C.F.R. § 493.803. The surveyors allege specifically that Petitioner did not successfully participate in: (1) chemistry – one of Petitioner's two CLIA certified specialties; and (2) four of twenty-five analytes in the subspecialty of routine chemistry. The surveyors examined PT scores from the American Proficiency Institute (API). The surveyors found that in the subspecialty of routine chemistry, Petitioner had scores of 0 percent for the analyte chloride for the third test event of 2011 and the second test event of 2012; 0 percent for HDL cholesterol for the third test event of 2011 and the first and second test events of 2012; 20 percent for sodium for the third test event of 2011 and the first and second test events of 2012; and 20 percent for digoxin for the first and second test events of 2012. CMS Ex. 2 at 1-3. The surveyors' findings are consistent with the API "Failures Summary," except that report also shows that Petitioner scored 60 percent on the first test event for 2012 for the analyte chloride. CMS Ex. 20. Petitioner did not object to CMS Ex. 20 and has not disputed the accuracy of the findings reported in CMS Ex. 20. Petitioner does not dispute, in either the request for hearing or in its prehearing brief and opposition to the motion for summary judgment, that the proficiency test failures alleged by CMS and reported in CMS Ex. 20 occurred and are accurately reported. In paragraph 3 of its prehearing brief, Petitioner acknowledges that proficiency test failures occurred. Petitioner offers explanations for why the failures occurred, which are analyzed hereafter.

Because Petitioner does not dispute the evidence of its unsatisfactory PT scores, or that its participation in proficiency testing was unsatisfactory as alleged by the surveyors in the SOD and as reflected in CMS Ex. 20, there is no genuine dispute as to the material facts. CMS has made a prima facie showing of condition-level noncompliance with 42 C.F.R. § 493.803. The regulation provides:

> Condition: Successful participation.
>
> (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.
>
> (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part.

> (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists:
>
> > (1) There is immediate jeopardy to patient health and safety.
> >
> > (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.
> >
> > (3) The laboratory has a poor compliance history.

42 C.F.R. § 493.803.

There is no dispute that Petitioner applied for and received a CLIA certificate to perform nonwaived testing, specifically routine chemistry, among others. CMS Exs. 7, 9. There is no dispute that CMS approved proficiency testing by API. There is no dispute that Petitioner failed to successfully participate in proficiency testing for routine chemistry by failing to achieve a score of 80 percent or better for each analyte as detailed above. Accordingly, there is a prima facie showing of noncompliance with the condition-level requirement of 42 C.F.R. § 493.803, and CMS has authority pursuant to 42 C.F.R. § 493.803(b) to impose sanctions. The regulation grants CMS discretion to take alternative actions for initial unsuccessful performance in limited cases. 42 C.F.R. § 493.803(c). However, CMS Ex. 14, which is also not disputed, shows prior unsuccessful participation in the second test event for 2011, albeit in the specialty of hematology. Further, the surveyors declared immediate jeopardy. Thus, the alternatives to sanctions set forth in 42 C.F.R. § 493.803(c), i.e. training and technical assistance, are not authorized in this case. I further note that CMS's determination as to which principal and alternative sanctions to impose and the determination that Petitioner's deficiencies pose immediate jeopardy are not initial determinations subject to being reviewed. 42 C.F.R. § 493.1844(c)(4), (6).

Having determined that there are no genuine disputes as to the material facts that establish a prima facie showing of noncompliance with 42 C.F.R. § 493.803, it is necessary to analyze Petitioner's alleged defenses. Petitioner has not presented affidavits or declarations in support of its arguments and did not file other evidence in support of its opposition to the CMS motion for summary judgment. It is required on summary

judgment that I view all evidence in a light most favorable for the Petitioner and draw all inferences in Petitioner's favor. I am not to judge credibility or weigh the evidence on summary judgment. Therefore, for purposes of ruling on summary judgment, I accept as true Petitioner's allegations of fact in its request for hearing and prehearing brief. I conclude that, even if I accept Petitioner's allegations of fact as true, as a matter of law Petitioner can establish no defense to excuse its noncompliance with the condition-level requirement established by 42 C.F.R. § 493.803.

Betty Hanks, Petitioner's Laboratory Director, asserts in the request for hearing that when two employees left employment at the laboratory they took items that would be needed for inspection. She states that city police were notified on July 30, 2012. Request for Hearing (RFH) at 1; P. Br. at 2. Ms. Hanks does not assert that there is any connection between the materials allegedly stolen and the PT failures and noncompliance with 42 C.F.R. § 493.803. There is no favorable inference to be drawn for Petitioner.

Ms. Hanks asserts in the request for hearing (RFH at 1) and the prehearing brief (P. Br. at 1) that the survey team was led by a man against who she had previously filed sexual harassment charges and that she had been promised by the state agency that he would not be permitted to survey Petitioner. Ms. Hanks does not assert that the survey team composition had any impact upon the unsatisfactory PT scores, which occurred months prior to the survey.

Ms. Hanks asserts that remedial action was implemented for the failed proficiency testing subsequent to the survey and that Petitioner's PT scores were acceptable for two events in a row. RFH at 2. The fact that Petitioner had subsequent satisfactory PT scores is accepted as true, but Petitioner points to no authority that supports an argument that the subsequent scores deprive CMS of the authority to suspend, limit, or revoke Petitioner's CLIA certificate. Ms. Hanks also asserts that Petitioner was complying with the requirements of CLIA, at least as of the date of the request for hearing, and she requested reinstatement of Petitioner's CLIA certificate on that basis. As already noted, if I conclude that CMS had a basis to impose principal and alternative sanctions, I have no authority to review the CMS choice of sanctions. 42 C.F.R. § 493.1844(c)(4). The CMS "determination not to reinstate a suspended CLIA certificate because the reason for the suspension had not been removed or there is insufficient assurance that the reason will not recur" is also not subject to my review. 42 C.F.R. § 493.1844(c)(3). *Associated Internists, P.C.*, DAB No. 2298, at 6 (2010); *HRT Lab., Inc.*, DAB No. 2118, at 10-11 (2007).

Ms. Hanks asserts that CMS requested corrective action related to the unsatisfactory PT performance, even though Ms. Hanks states that she was previously advised that no corrective action would suffice. She asserts that normal procedure would have been for Petitioner to have been advised of the unsatisfactory PT scores and permitted a period to return to compliance, but that did not happen in this case. P. Br. at 2. Ms. Hanks

describes the procedure at 42 C.F.R. § 493.803(c). As already noted, 42 C.F.R. § 493.803(c) does not apply in this case due to the declaration of immediate jeopardy and Petitioner's history of noncompliance with the PT participation requirement. Even if 42 C.F.R. § 493.803(c) could have been applied as a matter of discretion by CMS, the decision not to apply 42 C.F.R. § 493.803(c) is not a reviewable initial decision listed in 42 C.F.R. § 493.1844(b). 42 C.F.R. § 493.1844(c). Furthermore, even if remedial action was permitted or directed by CMS, remedial action does not excuse unsuccessful PT participation. *Sonali Diagnostic Lab.*, DAB No. 2008, at 7 (2006). Therefore, this issue must be resolved against Petitioner as a matter of law, as the law precludes review of this exercise of discretion by CMS.

Ms. Hanks also asserts that extreme circumstances occurred during the period of the unsatisfactory PT performance. For purposes of summary judgment, I accept her assertions that certain incidents or events occurred are true. The gist of Ms. Hanks' argument is that attempted murder, death, disability, and suicide distracted her from running Petitioner, and she trusted one who was not reliable to oversee the laboratory. While Ms. Hanks offers an enlightening explanation for Petitioner's unsuccessful PT participation, she cites no legal authority for the proposition that Petitioner's condition-level noncompliance with 42 C.F.R. § 493.803 may be or should be excused simply because she was not fully executing her duties to oversee laboratory operations as Petitioner's laboratory director.

I conclude, after review of Petitioner's assertions of facts and arguments, that Petitioner has failed, as a matter of law, to establish any defense to the prima facie showing of a condition-level violation of 42 C.F.R. § 493.802. Accordingly, I conclude that CMS had a basis to suspend and revoke Petitioner's CLIA certificate.

III. Conclusion

For the foregoing reasons, Petitioner's CLIA certificate is revoked, effective the date of this decision.

/s/
Keith W. Sickendick
Administrative Law Judge