Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Amanda LaComb, M.D., APMC,
(CLIA No. 19D0964266),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-622

Decision Number CR3675

Date: March 4, 2015

DECISION

I deny the Centers for Medicare & Medicaid Services' (CMS's) motion to dismiss and grant CMS's motion for summary judgment. The undisputed evidence establishes that CMS had the authority to revoke Petitioner Amanda LaComb, M.D., APMC's certificate under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for a two-year period because Amanda LaComb, M.D., operated another laboratory that had its CLIA certificate revoked.

I. Background

The following facts are undisputed unless otherwise noted. Petitioner is a laboratory owned by Dr. LaComb under CLIA certificate number 19D0964266. Dr. LaComb is a physician licensed to practice medicine in Louisiana and specializes in family medicine. Her office is located at 1322 Elton Road, Suite F, Jennings, Louisiana. Petitioner Exhibit (P. Ex.) 1 (Affidavit of Amanda LaComb, M.D.), at 1-2 ¶¶ 1, 6. Dr. LaComb was also the laboratory director of record for another laboratory in Jennings, which performed moderate complexity testing and was owned by Antonio Rogers under the name Lake

Area Laboratories (CLIA number 19D2002974) (Jennings Lake Area Laboratory).[1] CMS Ex. 1, at 2; CMS Ex. 4, at 1. Petitioner is a "CLIA –waived" laboratory,[2] and Dr. LaComb contracted with Lake Area Laboratories to provide "CLIA-certified" services. P. Br. at 2 and n.2; P. Ex. 1, at 2 ¶¶ 5-7; CMS Ex. 1, at 2 (Dr. LaComb's statement that she contracted with Lake Area Laboratories to operate the Jennings Lake Area Laboratory "to assist in urine drug screening in an effort to minimize diversion of narcotics in [her] rural practice.").

By letter dated April 30, 2013, CMS notified Antonio Rogers, as owner, and Dr. LaComb, as laboratory director, that a second onsite revisit survey by the Louisiana Department of Health and Hospitals (state agency) found three condition-level deficiencies at the Jennings Lake Area Laboratory. CMS sent the notice letter to them at 1322 Elton Road, Ste. F, Room 9, Jennings, Louisiana, Dr. LaComb's practice location. In the notice letter, CMS stated that it was sanctioning the Jennings Lake Area Laboratory based on the cited deficiencies, including revocation of its CLIA certificate effective July 2, 2013, unless Dr. LaComb (or Mr. Rogers) requested a hearing by July 1, 2013. CMS Ex. 4, at 1-5. The notice letter specifically indicated that CMS did not find the Jennings Lake Area Laboratory met the condition requirements for a laboratory director in a moderate complexity laboratory. Dr. LaComb admits receiving the notice letter on May 22, 2013. P. Ex. 1, at 4 ¶ 11; CMS Ex. 4, at 6. Dr. LaComb admits she did not file a hearing request prior to the date of revocation on behalf of the Jennings Lake Area Laboratory, and CMS did not receive any other hearing request on behalf of the Jennings Lake Area Laboratory. CMS Ex. 1, at 2-3; P. Ex. 1, at 4-5 ¶¶ 12, 13.

By letter dated July 30, 2013, CMS notified Antonio Rogers, as owner, and Dr. LaComb, as laboratory director, that the Jennings Lake Area Laboratory's CLIA certificate had been revoked because no appeal had been filed by the July 1, 2013 deadline and because the laboratory was closed. CMS Ex. 5, at 1-3. The notice stated:

> Please note that sections 42 U.S.C. 263a(i)(3) and 42 C.F.R. 493.1840(a)(8) prohibit the owner(s) or operator(s) (including director – see 42 C.F.R. 493.2) of laboratories that have had their certificates revoked from owning or operating (or directing) a laboratory for at least two years from the date of

[1] Lake Area Laboratories apparently performed testing at several locations other than Petitioner's office and listed Petitioner as their laboratory director, including Crowley, Louisiana (CLIA number 19D2003420); Plaquemine, Louisiana (CLIA number 19D2038508); and Baton Rouge, Louisiana (CLIA number 19D2007919). CMS Ex. 4, at 7-21.

[2] CLIA waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result." 42 U.S.C. § 263a(d)(2),(3).

> the revocation. This prohibition applies to the owner(s) as well as the director at the time that the deficiencies were found which led to the revocation action. **The two year period is in effect from July 2, 2013 to July 1, 2015.**

CMS Ex. 5, at 1 (emphasis in original).

By letter dated July 30, 2013, CMS sent Petitioner notice that it was revoking its CLIA certificate (number 19D0964266) for two years because Dr. LaComb, as Petitioner's owner, was the laboratory director of the four Lake Area Laboratories whose CLIA certificates had been revoked, including the Jennings Lake Area Laboratory.[3] CMS explained that the revocation was based on the prohibition on a laboratory owner or operator whose CLIA certificate has been revoked from owning or operating another laboratory for two years from the date of revocation. CMS stated it would impose this revocation by September 30, 2013, or after a hearing decision if Petitioner requested a hearing. CMS informed Petitioner that its hearing request should be sent to the Departmental Appeals Board, Civil Remedies Division (CRD) and to S.P., a CMS laboratory consultant working in the CLIA program office in Dallas. CMS Ex. 2. On September 24, 2013, Dr. LaComb faxed a letter to S.P. explaining why revocation of Petitioner's CLIA certificate should not take place and asking CMS to "reconsider" the revocation. CMS Ex. 13, at 3; CMS Ex. 1, at 2-3.

On January 8, 2014, CMS sent Petitioner notice that its CLIA certificate (number 19D0964266) was revoked for a two-year period, from January 8, 2014, through January 7, 2016. CMS noted that Petitioner's deadline for filing a hearing request was September 30, 2013, but CMS had "not received a formal hearing request" from Petitioner. CMS Ex. 3.

Dr. LaComb responded to the January 8, 2014 notice and stated that she had timely filed a hearing request on Petitioner's behalf by mailing a hearing request to CRD and by faxing and mailing the request to the CMS CLIA program office. P. Ex. 1, at 4-5 ¶ 14; CMS Ex. 1. Although CRD never docketed, or has any record of receiving, any request for hearing from Petitioner, the CMS CLIA program did receive the September 24, 2013 responsive letter from Dr. LaComb concerning her laboratory's revocation. Based on this letter, CMS postponed the revocation of Petitioner's CLIA certificate. CMS Ex. 13, at 3.

On January 16, 2014, CMS forwarded the correspondence S.P. received regarding Petitioner's revocation to CRD. CRD docketed Petitioner's two documents as Petitioner's hearing request, and the case was assigned to me for hearing and decision.

---

[3] I need only consider the revocation of the Jennings Lake Area Laboratory in this decision.

I issued an Acknowledgment and Initial Pre-hearing Order setting out a prehearing briefing schedule. CMS filed a motion to dismiss and, in the alternative, a motion for summary judgment with supporting brief (CMS Br.) and 13 proposed exhibits (CMS Exs. 1-13). Petitioner filed an opposition to the motion to dismiss (P. Opp.), a prehearing brief (P. Br.), and one proposed exhibit (P. Ex. 1).

II. CLIA Authority

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* § 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 the public health of all Americans. *See* H.R. REP. No. 100-899, *as reprinted in* 1988 U.S.C.C.A.N. 3828, 3839. CMS certifies a laboratory under CLIA only if it meets statutory and regulatory requirements. 42 U.S.C. § 263a(f)(1)(E); 42 C.F.R. § 493.1 *et. seq.* Pursuant to CLIA, the Secretary of Health and Human Services (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.

Implementing regulations specify the standards and conditions of certification that a laboratory must meet to achieve compliance. 42 C.F.R. Part 493. The regulations confer broad authority on CMS to ensure that laboratories perform as Congress intended, including 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 or state monitoring. 42 C.F.R. § 493.1806.

A laboratory or, under circumstances specified in 42 U.S.C. § 263a(i)(1), a laboratory owner or operator, is entitled to reasonable notice and an opportunity for a hearing before an administrative law judge (ALJ) to contest imposition of CLIA remedies and may request review of the ALJ's decision by the Departmental Appeals Board. The CLIA regulations incorporate by reference the hearing procedures and the request for review provisions in 42 C.F.R. Part 498, subparts D and E. 42 C.F.R. § 493.1844.

III. Discussion

A. Issues Presented

1) Whether Petitioner's request for hearing should be dismissed; and, if not,

2) Whether CMS is authorized to revoke Petitioner's CLIA certificate number 19D0964266.

B. Findings of Fact & Conclusions of Law

1. I deny CMS's motion to dismiss because CMS received a timely hearing request that identified Dr. LaComb's role in the Jennings Lake Area Laboratory as an appealable issue.

CMS moves to dismiss this case because Petitioner failed to timely request a hearing from CRD within 60 days, and the time for filing has not been extended. *See* 42 C.F.R. § 498.70. S.P. admits that the CMS CLIA program received Dr. LaComb's letter (arguing why revocation of Petitioner's CLIA certificate should not take place) on September 24, 2013, which was within the 60-day deadline. CMS Ex. 13, at 3 ¶ 8. CMS waited some time but still revoked Petitioner's CLIA certificate on January 8, 2014. CMS Ex. 3. Dr. LaComb avers that she filed a timely hearing request with CRD (received by CMS on September 24, 2013) but does not know why CRD did not receive it. P. Ex. 1, at 4-5 ¶¶ 14, 16. S.P. received faxed copies of both requests from Dr. LaComb on January 8, 2014, and S.P. forwarded them to CRD. CMS Ex. 13, at 3 ¶¶ 8, 9. Because it is undisputed that the CMS CLIA program office timely received the letter from Petitioner arguing against the revocation, I am extending the time for Petitioner to file a hearing request and accepting the two documents CRD received from S.P. in January 2014 as Petitioner's hearing request in this case. CMS Ex. 1; P. Ex. 1, at 4-5 ¶¶ 14-16.

In the alternative, CMS argues that if I do not dismiss Petitioner's hearing request for lack of timeliness, I must dismiss Petitioner's hearing request because Petitioner failed to identify the findings of fact and conclusions of law with which it disagreed. In particular, CMS asserts that Petitioner did not challenge any of the allegations in CMS's July 30, 2013 revocation letter, including that: Dr. LaComb is the owner and operator of Petitioner's CLIA certificate 19D0964266; Dr. LaComb was the laboratory director of the Jennings Lake Area Laboratory; and CMS revoked the CLIA certificates for the Lake Area Laboratory locations including the Jennings Lake Area Laboratory.

Dr. LaComb's letter to S.P. does include an acknowledgment that, for the Jennings Lake Area Laboratory, she "was responsible for the lab as the laboratory director on file." CMS Ex. 1, at 3. However, she appears to dispute whether she was always, in fact, a director or operator of the Jennings Lake Area Laboratory:

> Around March of 2013, I was informed by the owner that they would be seeking a "High Complexity" level for their labs and they had hired another physician to be the laboratory director because only a pathologist can serve

> as a laboratory director for a "High Complexity" lab. In my mind I was no longer serving as laboratory director once this other individual was hired although I have nothing in writing to support my impression.

CMS Ex. 1, at 2. I thus find that Dr. LaComb intended to challenge CMS's determination that she was the laboratory director and operator of the Jennings Lake Area Laboratory. *See* 42 C.F.R. § 498.40. Therefore, I deny CMS's motion to dismiss Petitioner's hearing request.

2. Summary judgment is appropriate.

Summary judgment is appropriate if "the record shows that there is no genuine issue as to any material fact, and the moving party is entitled to judgment as a matter of law." *Senior Rehab. & Skilled Nursing Ctr.*, DAB No. 2300, at 3 (2010) (citations omitted). The moving party must show that there are no genuine issues of material fact requiring an evidentiary hearing and that it is entitled to judgment as a matter of law. *Id.* If the moving party meets its initial burden, the non-moving party must "come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita Elec. Indus. Co. v. Zenith Radio*, 475 U.S. 574, 587 (1986). "To defeat an adequately supported summary judgment motion, the non-moving party may not rely on the denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a material fact -- a fact that, if proven, would affect the outcome of the case under governing law." *Senior Rehab.*, DAB No. 2300, at 3. To determine whether there are genuine issues of material fact for hearing, an ALJ must view the evidence in the light most favorable to the nonmoving party, drawing all reasonable inferences in that party's favor. *Id.* When ruling on a motion for summary judgment, an ALJ may not assess credibility or evaluate the weight of conflicting evidence. *Holy Cross Vill. at Notre Dame, Inc.*, DAB No. 2291, at 5 (2009).

Here, CMS has moved for summary judgment and asserted that the material facts of the case are undisputed. While Petitioner denies certain of the "undisputed material facts" adduced by CMS (P. Opp. at 4-5), as I explain below, its challenges to these facts are not material to my decision.

3. A person who has operated a laboratory that had its CLIA certificate revoked may not own or operate another CLIA-certified laboratory for two years.

CLIA provides the following with respect to the owners and operators of noncompliant laboratories:

> (3) Ineligibility to own or operate laboratories after revocation

> No person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section.

42 U.S.C. § 263a(i)(3).

CMS may suspend, limit, or revoke a laboratory's CLIA certificate of any type if it finds that the owner or operator has:

> [w]ithin the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. (This provision applies only to the owner or operator, not to all of the laboratory's employees.).

42 C.F.R. § 493.1840(a)(8).

> ***4. The undisputed evidence demonstrates that CMS is authorized to revoke Petitioner's CLIA certificate because, as the laboratory director of record for the revoked Jennings Lake Area Laboratory, Dr. LaComb was necessarily responsible for overall operations of that laboratory.***

The implementing regulations generally define an "operator," as:

> *Operator* means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes –
>
> (1) A director of the laboratory if he or she meets the stated criteria . . . .

42 C.F.R. § 493.2. A CLIA certified laboratory that performs moderate complexity testing, however, is specifically required to have a qualified laboratory director who is responsible for the overall operation and administration of the laboratory and for assuring compliance with the applicable regulations. 42 C.F.R. §§ 493.1403, 493.1407.

Dr. LaComb, as its uncontested laboratory director of record, does not dispute that she received proper notice of the proposed revocation of the Jennings Lake Area Laboratory's CLIA certificate in May 2013, allowing her time to file a request for hearing before CMS revoked that laboratory's CLIA certificate. This notice included CMS's finding that the laboratory director did not meet the condition requirements for a moderate complexity laboratory. CMS Ex. 4, at 1, 2. Neither Dr. LaComb nor Mr.

Rogers appealed the revocation decision, it became final, and I will not now reconsider her involvement as the director in that laboratory. *See* P. Br. at 4-5; P. Opp at 5-7. As the undisputed laboratory director of record for a laboratory conducting moderate complexity testing, Dr. LaComb was ultimately responsible for the operations of the Jennings Lake Area Laboratory and is now necessarily banned from owning or operating another laboratory.

Petitioner argues that Dr. LaComb does not meet the definition of an "operator" in her position as the laboratory director of the Jennings Lake Area Laboratory because she did not oversee any laboratory operations or agree to assume responsibility for "all facets of the operation." Instead, Petitioner explains the owner, Antonio Rogers, and a technical consultant were responsible for "some facets" of the operation. P. Br. at 4; P. Ex. 1, at 2-3 ¶¶ 7-10. It is true that the laboratory director of a moderate complexity laboratory may, in certain circumstances, delegate responsibilities to qualified technical consultants, clinical consultants, and testing personnel. 42 C.F.R. § 493.1407(a). However, the laboratory director of a moderate complexity laboratory remains responsible for ensuring that all duties are properly performed. 42 C.F.R. § 493.1407(b). Further, Dr. LaComb was among the "group of individuals," including Mr. Rogers and the unnamed technician, that did oversee all facets of the Jennings Lake Area Laboratory's operations, and she was specifically responsible for the safety and reliability of the testing results. *See* CMS Ex. 1, at 2. Therefore, assuming for summary judgment purposes that Dr. LaComb did not individually oversee all facets of the Jennings Lake Area Laboratory, she was still ultimately responsible for the Jennings Lake Area Laboratory's operations as the laboratory director of record, was part of the group of individuals that did oversee all facets of the laboratory, and thereby met the definition of an "operator" of the Jennings Lake Area Laboratory.

Even if I were to reconsider that underlying determination that necessitates the instant revocation, I do not find her descriptions of her involvement as creating a genuine issue of material fact. For example, in her letter to S.P. from the CMS CLIA program office, Dr. LaComb describes that, as laboratory director for the Jennings Lake Area Laboratory, she:

> completed the laboratory director course and served as laboratory director for the lab in my office. I reviewed the CLIA Improvement amendments, "Laboratory Director Responsibilities", and the "Interpretive Guidelines for Laboratories" from the CMS CLIA website and adhered to the interpretations therein. I performed my duties in good faith to the best of my abilities based on the training and material available to me to perform my job. I oversaw policies and procedures, proficiency testing of the employees, evaluated proficiency testing results and reports, reviewed any problem logs or concerns, and reviewed patient reports for accuracy and appropriateness. I was presented with materials that indicated to me that

> there were quality assurance measures in place, that there was adequate and appropriate safety and quality in the lab operation. Materials presented to me by those who were under my direction indicated that the day to day operations were within the guidelines for appropriate, quality and safe operations of the lab. The owner hired a technical consultant to respond to deficiencies and these were addressed by the technical consultant. What was presented to me was a reasonable response to those issues when applicable and brought to my awareness.

CMS Ex. 1, at 2.

By her own description, Dr. LaComb "oversaw policies and procedures, proficiency testing of the employees, evaluated proficiency testing results and reports, reviewed any problem logs or concerns, and reviewed patient reports for accuracy and appropriateness." CMS Ex. 1, at 2.

Dr. LaComb generally avers in her affidavit that sometime in 2013 the owner of the Jennings Lake Area Laboratory informed her he was retaining another laboratory director and that her "service as laboratory director for the laboratory in my office terminated at that point." P. Ex. 1, ¶ 7. Petitioner's statement does not constitute a specific fact creating a genuine issue that would preclude me from ruling on CMS's motion for summary judgment. Instead, Petitioner offers only a vague and unsupported statement failing to describe, among other things, exactly when in 2013 a new laboratory director was actually hired, who that person was, whether he or she visited the Jennings Lake Area Laboratory, or whether Dr. LaComb or someone else was responsible for training and transitioning that person at the Jennings Lake Area Laboratory. Dr. LaComb even admits in her hearing request that she has "nothing in writing to support [her] *impression*." CMS Ex. 1, at 2 (emphasis added). Dr. LaComb's vague affidavit does not defeat CMS's adequately supported summary judgment motion. *See Matsushita Elec. Indus. Co.*, 475 U.S. 574, 586-87 (requiring the non-moving party to come forward with specific facts to preclude a decision on summary judgment).

I also find unavailing Petitioner's argument that Dr. LaComb's agreement to serve as laboratory director of the Jennings Lake Area Laboratory is void *ab initio* because it was induced by fraud. Petitioner asserts that Dr. LaComb never agreed to serve as laboratory director for three other Lake Area laboratories that CMS also revoked or for any laboratory location other than the Jennings Lake Area Laboratory and Petitioner's laboratory. P. Ex. 1, at 2 ¶ 5; P. Brief at 3. Petitioner argues that Mr. Rogers deceived Dr. LaComb and that she would not have agreed to contract with him for the Jennings Lake Area Laboratory if she knew he was going to list her as the laboratory director for Lake Area Laboratories' Baton Rouge, Crowley, and Plaquemine locations. P. Br. at 3-4.

Nonetheless, even assuming for purposes of summary judgment that her affiliations with the other laboratories were fraudulently listed, it is uncontested that her involvement with the Jennings Lake Area Laboratory was not obtained by fraud, and that one laboratory's revocation is sufficient to sustain the revocation of Petitioner's certificate here.

Finally, Petitioner argues Congress enacted the two-year ban on operators from CLIA-revoked laboratories to specifically prevent those operators from simply opening another laboratory. Petitioner argues that, as a CLIA-waived laboratory wholly unrelated to, and at a different complexity level from, the Jennings Lake Area Laboratory, the revocation of Petitioner's CLIA certificate does not serve the purpose for which section 263a(i)(3) was enacted. Petitioner argues that because Dr. LaComb, who operated Petitioner (a CLIA-waived laboratory) for over ten years, has no intention of applying for a CLIA certificate for a higher complexity laboratory or of opening or becoming a laboratory director of another laboratory, there is no purpose to be served by the two-year ban. P. Br. at 5-6. Even if I assume for summary judgment purposes that Dr. LaComb has no intentions of operating any other laboratory besides the one at issue here, I have no discretion to consider Petitioner's argument to exempt her from the ban. Once the Jennings Lake Area Laboratory's CLIA certificate was revoked, Dr. LaComb, as its uncontested laboratory director of record, was subject to the two-year ban by operation of law, a legal requirement that I cannot ignore. 42 U.S.C. § 263a(i)(3); 42 C.F.R. § 493.1840(a)(8).

IV. Conclusion

I grant summary judgment to CMS to revoke Petitioner's CLIA certificate. Dr. LaComb is Petitioner's owner and operator. The undisputed facts demonstrate that Dr. LaComb did not contest CMS's previous revocation determination regarding the Jennings Lake Area Laboratory, and, as the laboratory director of record for a laboratory that has a CLIA certificate to allow moderate complexity testing, she was responsible overall as an operator of that laboratory. Dr. LaComb is necessarily banned from owning or operating another laboratory for a two-year period.

/s/
Joseph Grow
Administrative Law Judge