Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Southlake Emergency Care Center
(CLIA #45D1021990),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-10-877

Decision No. CR2300

Date: January 10, 2011

DECISION

For the reasons set forth below, I grant the Centers for Medicare and Medicaid Services' (CMS's) motion for summary judgment. The undisputed evidence establishes that the owner of Southlake Emergency Care Center (Petitioner) was also the owner of Coppell Minor Emergency Center, LLC (Coppell Laboratory). CMS previously revoked the Clinical Laboratory Improvement Amendments (CLIA) certificate of Coppell Laboratory. I conclude that CMS therefore had authority to revoke Petitioner's CLIA certificate, pursuant to 42 C.F.R. § 493.1840(a)(8).

I. Background

On August 9, 2010, Departmental Appeals Board (Board) Member Leslie A. Sussan issued an Acknowledgment and Pre-Hearing Order, setting procedures for this appeal.[1] CMS submitted a "Motion for Summary Judgment, or Alternatively, Motion for Summary Disposition and/or Pre-Hearing Brief" (CMS Br.), dated September 8, 2010, and five exhibits (CMS Exs. 1-5). Petitioner submitted a response to CMS's motion (P.

[1] Pursuant to 42 C.F.R. § 498.44, a member of the Board may be designated to hear appeals taken under part 498.

Br.), dated October 7, 2010, and attached one exhibit (P. Ex. A). CMS submitted a reply to Petitioner's response (CMS Reply), dated November 5, 2010. This case was transferred to me on October 25, 2010. Neither party objected to the admission of any exhibit. Accordingly, I admit all of the parties' exhibits as evidence.

I set out here the material facts that are not in dispute. Petitioner, a clinical laboratory in Southlake, Texas with CLIA Certificate No. 45D1021990, is owned and operated by Charles J. O'Hearn, M.D. (Dr. O'Hearn). Dr. O'Hearn also owned and operated Coppell Laboratory in Coppell, Texas with CLIA Certificate No. 45D0996638. On February 18, 2010, the Texas Department of State Health Services (DSHS) conducted a recertification of Coppell Laboratory and determined that the facility was not in compliance with certain CLIA regulations. DSHS cited several deficiencies. CMS Ex. 4. On March 5, 2010, DSHS sent Dr. O'Hearn a written notice requesting a plan of correction (POC) for the deficiencies cited. *See* CMS Ex. 2, at 1. On April 20, 2010, CMS issued a notice letter proposing revocation of Coppell Laboratory's CLIA certificate, effective June 22, 2010. CMS Ex. 2, at 3. The notice letter informed Dr. O'Hearn of his appeal rights to challenge the proposed revocation of Coppell Laboratory's CLIA certificate for failing to meet CLIA conditions. CMS Ex. 2, at 4. The notice letter also informed Dr. O'Hearn that it was the fourth request for an acceptable POC. CMS Ex. 2, at 1. Specifically, the April 20, 2010 letter stated, in part:

> Your laboratory's CLIA certificate will be revoked effective **June 22, 2010** if one or all of the following occurs:
>
> - a request for a hearing is not received by **June 21, 2010**; or
> - DSHS finds continued condition level non-compliance conditions on the revisit; or status at the time of the revisit escalates to an immediate jeopardy; or
> - CMS and the State do not receive an AOC [allegation of compliance] and POC; or
> - the POC does not ensure correction of the condition level deficiencies.

CMS Ex. 2, at 3 (emphasis in original).

Dr. O'Hearn states that he submitted a POC for Coppell Laboratory on April 20, 2010, but then he closed Coppell Laboratory that same month, citing "the present economic conditions and shrinking healthcare reimbursements." Hearing Request at 1. Dr. O'Hearn did not surrender Coppell Laboratory's CLIA certificate to CMS. *See* CMS Br. at 6. On June 23, 2010, CMS issued a notice letter informing Dr. O'Hearn that CMS had revoked Coppell Laboratory's CLIA certificate effective June 22, 2010 due to the laboratory's failure to ensure correction of condition-level noncompliance and failure to file an appeal within sixty days from the notice of proposed revocation. CMS Ex. 3, at 2. Dr. O'Hearn did not request a hearing to appeal the revocation of Coppell Laboratory's CLIA certificate by June 21, 2010. Dr. O'Hearn explains that the revocation letter came

two months after he closed Coppell Laboratory for economic reasons, so it made no sense for him to appeal the certificate. Hearing Request at 1. In both the April 20, 2010 and the June 23, 2010 notice letters, CMS informed Dr. O'Hearn that 42 U.S.C. § 263a and 42 C.F.R. § 493.1840(a)(8) prohibit the owners or operators of laboratories that have had their CLIA certificates revoked from owning or operating a laboratory for at least two years from the date of the revocation. CMS Ex. 2, at 3-4; CMS Ex. 3, at 2.

By letter dated July 20, 2010, CMS proposed revocation of Petitioner's CLIA certificate. CMS Ex. 1, at 1. The letter stated that Petitioner's CLIA certificate would be automatically revoked on September 21, 2010. *Id.* at 2. Petitioner timely appealed its revocation. Petitioner's July 23, 2010 Hearing Request proposes that the revocation of Coppell Laboratory's CLIA certificate "be undone . . . ." Hearing Request at 2. Petitioner further requests that Coppell Laboratory be "closed" so that revocation of its certificate would not occur, and Petitioner would then be able to continue to operate. *Id.*

II. Applicable Legal 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. 899, *as reprinted in* 1988 U.S.C.C.A.N. 3828, 3839. CMS certification of a laboratory under CLIA depends on 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. § 493.1 *et seq.* Pursuant to CLIA, the Secretary of the Department 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.

The Secretary has exercised her authority under 42 U.S.C. § 263a(f) and issued regulations implementing CLIA. *See* 42 C.F.R. Part 493. The regulations specify standards and the specific conditions of certification that a laboratory must meet to achieve compliance. 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 monitoring by the state. 42 C.F.R. § 493.1806.

In addition to the sanctions directed against laboratories, CLIA provides the following with respect to the owners and operators of non-compliant 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).

The implementing regulations provide that CMS may suspend, limit, or revoke a laboratory's CLIA certificate, 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).

The Secretary has published policies that acknowledge a laboratory may withdraw from CLIA by going out of business. CMS State Operations Manual (SOM), section 6256. However, the Secretary has also established as policy that CMS may nevertheless revoke a laboratory's CLIA certificate after a laboratory has gone out of business, if it decides that the laboratory's performance warrants proceeding with the enforcement action. SOM, section 6256.3.

III. Issues

1) Whether Petitioner may contest CMS's revocation of its CLIA certificate.

2) Whether further discovery shall be permitted regarding the revocation of Coppell Laboratory's CLIA certificate.

3) Whether CMS is entitled to summary judgment.

IV. Applicable Standard

CMS's motion made clear that the summary disposition it seeks is in the nature of summary judgment. CMS Reply at 5. The Board stated the standard for summary judgment as follows:

> Summary judgment is appropriate when 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. . . . The party moving for summary judgment bears the initial burden of showing that there are no genuine issues of material fact for trial and that it is entitled to judgment as a matter of law. . . . 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. . . . In determining whether there are genuine issues of material fact for trial, the reviewer must view the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor.

Senior Rehab. and Skilled Nursing Ctr., DAB No. 2300, at 3 (2010) (citations omitted). The role of an administrative law judge (ALJ) in deciding a summary judgment motion differs from the ALJ's role in resolving a case after a hearing. The ALJ should not assess credibility or evaluate the weight of conflicting evidence. *Holy Cross Vill. at Notre Dame, Inc.*, DAB No. 2291, at 5 (2009).

V. Findings of Fact, Conclusions of Law, and Discussion

My conclusions are in the italicized headings followed by discussion.

1. Petitioner may appeal the initial determination of CMS to impose a sanction against it by revoking its CLIA certification.

CMS argues that Petitioner has no right to an appeal in this matter. CMS Br at 7-13. I disagree, however, and find that Petitioner does have the right to request a hearing. Federal regulations clearly provide that laboratories dissatisfied with an initial determination, such as the revocation of a laboratory's CLIA certificate because of noncompliance with CLIA requirements, have the right to appeal the adverse determinations by CMS. 42 C.F.R. § 493.1844(a), (b)(1).

The right to appeal is time-limited under the regulation, however. For that reason, I am precluded from reopening issues involving Coppell Laboratory's CLIA sanction in the instant appeal due to administrative finality. Dr. O'Hearn was afforded a sixty-day period to challenge the revocation of Coppell Laboratory's CLIA certificate, and he failed to file an appeal pursuant to 42 C.F.R. § 498.40. 42 C.F.R. § 493.1844(a)(2).

Although the revocation of Petitioner's CLIA certificate is based on the finalized revocation of another laboratory's CLIA certificate, the revocation of Petitioner's CLIA certificate is an initial determination subject to appeal. 42 C.F.R. § 493.1844(b)(1). That

appeal is not barred by principles of res judicata because CMS's authority to revoke Petitioner's certificate, as opposed to Coppell's, has never been litigated and has not become administratively final. Given the plain regulatory language, therefore, it is clear that Petitioner has the right to appeal the revocation of its CLIA certificate.

Therefore, I have jurisdiction to resolve this case, and dismissal is not appropriate.

2. No further discovery shall be permitted, as estoppel against the federal government is unavailable.

Petitioner requests "that the ALJ permit limited discovery of CMS's files to demonstrate that fundamental due process was denied [Dr. O'Hearn], regarding the Coppell Lab's revocation." P. Br. at 3. Petitioner states that "[u]pon communicating . . . that the Coppell Lab had ceased operations, CMS indicated that the matter could be resolved without revocation of the Southlake Lab's certificate by putting CMS on notice of the Coppell Lab's cessation of operations." P. Br. at 2-3. Petitioner further states:

> On or about July 7, 2010, CMS, by and through Patty Nath, inspected Southlake Lab. At that time, Ms. Nath advised O'Hearn that the impact of the revocation of Coppell Lab's certificate was that the Southlake Lab's certificate would be revoked. In response to Ms. Nath's advice and the receipt of CMS's notice of sanctions letter, O'Hearn contacted CMS's Emily Townsend. Ms. Townsend suggested that O'Hearn give notice that his intent was to surrender the Coppell Lab's certificate and that doing so would solve the issue of the potential of the Southlake Lab's certificate being revoked.

P. Br. at 2.

CMS argues that I do not have the authority to order discovery in these proceedings. CMS Reply at 2-4. However, as an ALJ assigned to this matter, I do have a duty to develop the record pursuant to 42 C.F.R. § 498.60. Nonetheless, I will not permit further discovery in this case because, even if Petitioner were to obtain evidence of the kind it seeks, such evidence could not affect the outcome here.

Petitioner asks me, in effect, to estop the government from applying federal law and regulations, based on the fact that Petitioner received information from a CMS employee indicating that surrendering the Coppell Laboratory's CLIA certificate would resolve the issue in the instant case. P. Br. at 2. Even if I accept as true that CMS provided bad advice to Petitioner, it is well-settled that the government cannot be estopped, even after providing bad advice. As the Board has repeatedly held, estoppel against the federal government, if available at all, is presumably unavailable absent "affirmative

misconduct." *See, e.g., Pacific Islander Council of Leaders*, DAB No. 2091, at 12 (2007); *Office of Pers. Mgmt. v. Richmond*, 496 U.S. 414, 421 (1990). Petitioner has not demonstrated that incorrect understandings of legal requirements on the part of CMS or its contractors rises to the level of affirmative misconduct. *See, e.g., Huron Potawatomi, Inc.*, DAB No. 1889, at 5 (2003) (holding allegation that incorrect advice was provided was not to be evidence of affirmative misconduct). No affirmative misconduct has been alleged here; therefore, I deny Petitioner's request for limited discovery of CMS's files because it would not alter my determination in this case.

Further, it is undisputed that Petitioner never acted upon the purported bad advice to give notice to CMS that it was surrendering its CLIA certificate.

3. CMS is entitled to summary judgment because undisputed facts demonstrate that the revocation of Petitioner's CLIA certificate was legally authorized.

It is undisputed that Dr. O'Hearn owned and operated both the Southlake Laboratory and the Coppell Laboratory, and CMS revoked Coppell Laboratory's CLIA certificate on June 22, 2010. The revocation of Coppell Laboratory's CLIA certificate triggers 42 U.S.C. § 263a(i)(3), which provides that "[n]o 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 C.F.R. § 493.1840(a)(8) is also triggered, which permits CMS to initiate adverse action to suspend, limit, or revoke the CLIA certificate of any laboratory if it is found that the laboratory's owner or operator owned or operated a laboratory that had its CLIA certificate revoked within the last two years.

Petitioner argues that CMS should not have revoked the CLIA certificate of the Coppell Laboratory because Dr. O'Hearn closed the Coppell Laboratory prior to the revocation of its CLIA certificate. *See* Hearing Request. The voluntary closure of a laboratory, however, does not preclude CMS from proceeding with revocation of the laboratory's certificate. The Board has held that revocation under such circumstances may form the basis of the two-year prohibition against that laboratory's owners or operators operating another CLIA laboratory. *Sentinel Med. Labs., Inc.*, DAB No. 1762 (2001), *aff'd, Teitelbaum v. Health Care Financing Admin.*, No. 01-70236 (9th Cir. Mar. 15, 2002), *reh'g denied*, No. 01-70236 (9th Cir. May 22, 2002). If laboratories were allowed to close to escape revocation and their owners to then open another laboratory, the relevant CLIA regulations would be null, and the government's enforcement powers could be evaded. As the ALJ explained in *Hematology & Oncology Servs.*:

> CLIA makes the Secretary responsible for protecting the public from laboratory owners who are not complying with CLIA but who attempt to evade the reach of enforcement authority by pulling up stakes and moving

> their operations elsewhere. CLIA could be rendered ineffective if a laboratory owner was able to avoid its enforcement provisions simply by closing the laboratory's doors.

Hematology & Oncology Servs., LLC, DAB CR1754-58, at 6 (2008).

After CMS revoked the Coppell Laboratory's CLIA certificate, Dr. O'Hearn was banned, by operation of law, from owning or operating a laboratory for a two-year period. I have no authority to declare the statute or the regulation invalid or ultra vires. *1866ICPayday.com, L.L.C.*, DAB No. 2289, at 14 (2009) ("An ALJ is bound by applicable laws and regulations and may not invalidate either a law or regulation on any ground."). Thus, CMS has the authority to revoke Petitioner's CLIA certificate pursuant to 42 C.F.R. § 493.1840(a)(8).

VI. Conclusion

After reviewing the evidence in the light most favorable to Petitioner, I conclude that the regulatory language is plain, and there is no genuine issue of material fact here. I therefore grant Summary Judgment to CMS because CMS acted within its regulatory authority to revoke Petitioner's CLIA certificate, pursuant to 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8).

/s/
Joseph Grow
Administrative Law Judge