Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
CARI Reproductive Institute,	)	Date: January 21, 2010
(CLIA Number: 14D1056871),	)	
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-09-407
	)	Decision No. CR2060
Centers for Medicare & Medicaid	)	
Services.	)	
	)	

DECISION

The certificate of registration issued to Petitioner, CARI Reproductive Institute, to engage in the testing of human specimens pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA)[1] is revoked. Pursuant to 42 C.F.R. §§ 493.1840(e) and 493.1844(d)(2), the revocation of Petitioner's CLIA certificate is effective the date of this decision. By operation of law, the owners and operators of Petitioner are prohibited from owning or operating a CLIA 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 pursuant to 42 U.S.C. § 263a(i)(3) – the date of this decision.

I. Background

Petitioner applied for a CLIA certificate on January 17, 2008 and was issued a certificate on February 27, 2008. Request for Hearing at 4; Centers for Medicare and Medicaid Services (CMS) exhibit (CMS Ex.) 9, at 5. Petitioner indicated in its application that it

[1] Codified at 42 U.S.C. §§ 263a, 1302, 1395x(e). "CLIA" when used in this decision refers to both statutory and regulatory provisions governing the program, unless otherwise indicated.

intended to conduct general immunology testing of approximately 200 samples annually. CMS Ex. 9, at 3. The Illinois Department of Public Health (state agency) conducted an initial survey of Petitioner's laboratory on July 21, 2008, and concluded that the laboratory failed to meet two condition-level requirements and numerous standard-level requirements that are cited in the Statement of Deficiencies dated July 21, 2008 (SOD). CMS Exs. 10, 11. The state agency notified Petitioner by letter dated August 4, 2008 of the results of the survey and that it could submit a plan of correction within ten days. CMS Ex. 4, at 6-8.

Petitioner advised the state agency by letter dated August 25, 2008, that because it was not provided with the required 10 days to correct and respond to the cited deficiencies, it was withdrawing its application for a CLIA certificate and that it would remain a research and development laboratory without performing any tests on patient samples. CMS Ex. 5. On October 24, 2008 a revisit survey was attempted at Petitioner's laboratory but the surveyors were informed by Petitioner's staff that the laboratory director was out of the country, they were asked to return at a later dated, and they were not allowed to review Petitioner's records to determine if Petitioner was in compliance with CLIA requirements. CMS Ex. 2, at 1; CMS Ex. 15.

CMS notified Petitioner by letter dated November 4, 2008, that based on the July 21, 2008 survey findings, Petitioner was found not to be in compliance with two condition-level requirements and numerous standard level requirements. Petitioner was further advised that its request to withdraw or limit its CLIA certification would not be considered a correction of the deficiencies found during the July 2008 survey and that Petitioner could submit an acceptable plan of correction within ten days or be subject to sanctions. CMS Ex. 1. Petitioner requested and was granted an extension of time to submit the plan of correction, and on December 5, 2008, Petitioner submitted its plan of correction. CMS Ex. 2, at 2; CMS Ex. 6; CMS Ex. 7, at 3; CMS Ex. 11.

CMS notified Petitioner by letter dated December 19, 2008 that its plan of correction was not acceptable. The letter advised Petitioner that it could provide additional information and the letter listed the additional information required. CMS Ex. 2, at 3-5. The letter further notified Petitioner that CMS proposed the following alternative and principal sanctions: a directed plan of correction effective January 3, 2009; suspension and revocation of Petitioner's CLIA certificate effective January 3, 2009 subject to any request for hearing filed by Petitioner; and cancellation of Petitioner's approval to receive Medicare payments for laboratory services performed on or after January 3, 2009. The laboratory was further advised that pursuant to 42 U.S.C. § 263a(i)(2)(A) and 42 C.F.R. § 493.1849(d)(2)(ii), if Petitioner failed to submit a credible allegation of compliance by December 29, 2008, the suspension of its CLIA certificate would become effective January 3, 2009, even if Petitioner did file a request for hearing. CMS Ex. 2, at 5-6.

Petitioner requested and was granted an extension of time to submit the additional information, and on January 19, 2009, Petitioner sent CMS its additional information. CMS Ex. 3, at 2; CMS Ex. 12. CMS then notified Petitioner by letter dated February 25, 2009 that its submission was not acceptable. The letter provided Petitioner with a detailed analysis of why Petitioner's submission was not acceptable. The letter further notified Petitioner that its CLIA certificate was revoked effective February 25, 2009, subject to the filing of a request for hearing. CMS Ex. 3, at 2.

Petitioner timely requested a hearing before an administrative law judge (ALJ) on April 23, 2009. Petitioner attached to its request for hearing documents marked as Exhibit A through Exhibit G (P. Exs. A through G) as well as various notice letters that were not marked as exhibits but are included in the CMS exhibits. The request for hearing was docketed and assigned to me on May 4, 2009 for hearing and decision. An Acknowledgement and Prehearing Order (Prehearing Order) was issued at my direction on May 4, 2009.

On September 1, 2009, CMS filed a motion for summary judgment (CMS Brief) with CMS Ex. 1 through CMS Ex. 19.[2] Petitioner filed a response in opposition to the CMS motion and a cross-motion for summary judgment on October 5, 2009 (P. Brief). Petitioner did not file any exhibits with its brief but did include an attachment titled *Waiver of Hearing*, waiving its right to hearing. CMS filed a motion for leave to file a reply brief with its reply brief on October 19, 2009 (CMS Reply). CMS's reply brief is accepted. No objections have been made and CMS exhibits 1 through 19 and Petitioner exhibits A through G are admitted and considered. Petitioner's waiver of its right to a hearing is accepted and this decision is based upon the documentary evidence and the pleadings of the parties.

II. Discussion

A. Applicable Law

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* section 353 of the Public Health Service Act, *codified at* 42 U.S.C. §§ 263a, 1302, 1395x(e). The purpose of CLIA is to ensure the accuracy and reliability of laboratory tests, and hence, the public health of all Americans. CLIA was intended by Congress to establish a single set of standards to govern all providers of laboratory services, including those which provide services to Medicare beneficiaries.

[2] On September 1, 2009, CMS moved for a stay of proceedings in this case until 30 days after my ruling on its motion for summary judgment. The CMS motion was denied on September 16, 2009.

See H.R. Rep. No. 100-899, 100th Cong. 2d Sess. 8, 18 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3839. CLIA grants the Secretary of Health and Human Services (the Secretary) broad enforcement authority, including the ability to suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more requirements for certification. The Secretary has exercised this authority under 42 U.S.C. § 263a(f) and issued regulations implementing CLIA. *See* 42 C.F.R. Part 493.

Under CLIA, the Secretary is authorized to inspect clinical laboratories and license them to perform tests. The Act prohibits a clinical laboratory from soliciting or accepting specimens for testing unless it has first received from the Secretary a certificate authorizing it to perform the specific category of tests that the laboratory intends to perform. 42 U.S.C. § 263a(b). The Act directs the Secretary to establish standards to assure that clinical laboratories certified by the Secretary perform tests that are valid and reliable. 42 U.S.C. § 263a(f).

The Secretary's regulations delegate to CMS broad authority to ensure that laboratories perform as Congress intended, including authority to inspect and sanction laboratories that fail to comply with the regulatory requirements. 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); 42 C.F.R. § 493.1 *et. seq*. Pursuant to the enforcement provisions of the regulations, CMS may impose principal or alternative sanctions when it finds that a laboratory has a "condition-level" deficiency. 42 C.F.R. § 493.1804(b)(2). Principal sanctions are suspension, limitation, or revocation of a CLIA certificate. 42 C.F.R. § 493.1806(b). Alternative sanctions are a directed plan of correction, state on-site monitoring, and a civil money penalty. 42 C.F.R. § 493.1806(c). Cancellation of Medicare payments is also authorized as a principal sanction when condition-level deficiencies are found (42 C.F.R. §§ 493.1807(a) and 493.1842(a)(2)) and required when CMS suspends or revokes a laboratory's certificate (42 C.F.R. § 493.1842(a)). Standard-level deficiencies are not an adequate basis for the imposition of a sanction, except when the laboratory fails to correct such deficiencies within 12 months after the last day of inspection. 42 C.F.R. § 493.1816(b).

Each condition-level requirement of the regulations represents a major division of laboratory services to be offered by the laboratory or establishes an important environmental protection for the laboratory. Since each "condition" represents a major division of laboratory services to be offered by the laboratory or an important safety requirement, it has been held that a failure by a laboratory to comply with even a single applicable condition can represent a critical breakdown in one of the major health care delivery or safety systems of the laboratory. *Ward General Practice Clinic*, DAB No. 1624, at 2 (1997). Therefore, violation of just one condition-level deficiency can be grounds for a principal sanction, including revocation of a laboratory's CLIA certificate.

42 C.F.R. § 493.1804(b); *Edison Medical Laboratories*, DAB No. 1713 (1999), *aff'd, Edison Medical Laboratories, Inc., v. Thompson*, 250 F.3d (3rd Cir. 2001).

If, on inspection, a laboratory is found to have condition-level deficiencies that pose immediate jeopardy, CMS requires the laboratory to take immediate action to remove the jeopardy and may impose alternative sanctions to assist. If immediate jeopardy is not removed, CMS may suspend or limit and later revoke the laboratory's CLIA certificate. CMS is also delegated authority to bring a civil suit for an injunction against a laboratory in specified circumstances where there is immediate jeopardy. 42 C.F.R. § 493.1812. Condition-level deficiencies that do not constitute immediate jeopardy and standard-level deficiencies that do not rise to condition-level, are treated differently and a laboratory is generally accorded 12 months to correct such deficiencies before action is taken to suspend, limit, or revoke the laboratory's CLIA certificate. 42 C.F.R. §§ 493.1814, 493.1816.

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 implementing 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 found in subpart D of Title 42, Part 498 are incorporated by reference. 42 C.F.R. § 493.1844(a)(2). The "suspension, limitation, or revocation of the laboratory's CLIA certificate . . . because of noncompliance . . ." is the first listed initial determination subject to hearing before an ALJ. 42 C.F.R. § 493.1844(b)(1). The imposition of alternative sanctions is also an initial determination subject to appeal (42 C.F.R. § 493.1844(b)(3)), but the determination as to which alternative sanctions to impose and the amount of the CMP to be imposed are not. 42 C.F.R. §§ 493.1844(b)(3) and (c)(4). The general rule is that suspension, limitation, or revocation of a CLIA certificate does not go into effect if appealed, and is not imposed until the ALJ issues a decision, unless CMS declares immediate jeopardy, or if the laboratory has refused a reasonable request for information and then there is no delay in the suspension or limitation of the offending laboratory's CLIA certificate. 42 C.F.R. §§ 493.1840(e), 493.1844(d)(2). Additionally, a laboratory may not appeal a determination by CMS not to reinstate a suspended CLIA certificate where CMS has concluded that the reason for the suspension had not been removed or that there is insufficient assurance that the reason for the suspension will not recur. 42 C.F.R. § 493.1844(c)(3). My decision is final unless one of the parties requests and receives review by the Departmental Appeals Board (Board). 42 C.F.R. § 493.1844(d)(4).

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

> 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).

The implementing regulations do not include any express provision implementing or imposing this two-year prohibition against an offending owner or operator. However, the 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).

CLIA does not include a definition of the term operator. However, the regulations define an "operator" as:

> 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. The "stated criteria" for a laboratory director to be considered an operator are those criteria described in the introductory sentence of the above-quoted section, *i.e.*, whether a person oversaw all facets of the operation of the laboratory and bore primary responsibility for the safety and reliability of the results of specimen testing performed in the laboratory. *Sentinel Medical Laboratories, Inc.*, DAB No. 1762, at 13 (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); *Sol Teitelbaum, M.D.*, DAB No. 1849, at 8, n.7 (2002). It is a condition-level requirement that a CLIA-certified laboratory have a qualified laboratory director who is required to assume oversight and

responsibility for the laboratory and the results of its testing. *See* 42 C.F.R. §§ 493.1403, 493.1405, 493.1407, 493.1441, 493.1443, and 493.1445. Thus, the regulation creates a rebuttable presumption that a laboratory director is an operator of the laboratory within the meaning of the regulations and CLIA.

The allocation of the burden of proof in an appeal of CMS's sanctions is set forth in *Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd, Hillman Rehabilitation Center v. HHS*, No. 98-3789 (GEB), slip. op. (D.N.J. May 13, 1999); *Edison Medical Laboratories, Inc.*, DAB No. 1713 (*Hillman* burden of proof applicable in CLIA appeals), *aff'd* 250 F.3d (3rd Cir.). CMS has the burden of coming forward with sufficient evidence to prove a prima facie case of noncompliance with one or more CLIA conditions. The petitioner then has the ultimate burden of showing by a preponderance of the evidence that it was not out of compliance with the conditions placed at issue by CMS in its prima facie case. Regarding the imposition of sanctions, the issue to be resolved by the ALJ is not whether CMS properly exercised discretion in imposing either principal or alternative sanctions, but rather, whether a basis existed for the imposition of sanctions under governing statutory and regulatory authorities based upon the evidence before the ALJ, *i.e.* the ALJ resolves these issues de novo. *Rustom Ali, Jahan Ferdous, and Scottsdale Medical Laboratory*, DAB 2016, at 20 (2006) *citing Emerald Oaks*, DAB No. 1800, at 16 (2001).

B. Issue

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

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

1. Petitioner has waived its right to an in-person hearing.

2. Petitioner does not dispute that it was not in compliance with the CLIA condition of participation established by 42 C.F.R. § 493.1441 (Laboratory Director, High-Complexity Testing).

3. Petitioner does not dispute that it was not in compliance with the CLIA condition of participation established by 42 C.F.R. § 493.1447 (Technical Supervisor, High-Complexity Testing).

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

5. Revocation of Petitioner's CLIA certificate is effective the date of this decision. 42 C.F.R. § 493.1838(d)(2)(ii).

6. Petitioner's owner and operator are prohibited from owning or operating a laboratory for at least a two-year period from the effective date of revocation. 42 U.S.C. § 263(a)(i)(3); 42 C.F.R. §§ 493.2, 493.1840(a)(8).

The surveyors concluded based upon the initial survey of Petitioner's laboratory completed on July 21, 2008, that Petitioner was not in compliance with two condition-level participation requirements established by 42 C.F.R. §§ 493.1441 and 493.1447. If founded, either violation is a sufficient basis for suspension and revocation of Petitioner's CLIA certificate. 42 C.F.R. § 493.1804(b); *Edison Medical Laboratories, Inc*., DAB No. 1713; *Ward General Practice Clinic*, DAB No. 1624.

The regulation at 42 C.F.R. § 1441 provides:

> Sec. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
>
> The laboratory must have a director who meets the qualification requirements of Sec. 493.1443 of this subpart and provides overall management and direction in accordance with Sec. 493.1445 of this subpart.

Section 493.1445 lists the laboratory director's responsibilities. The surveyors allege that the regulation was violated based on a lack of technical oversight, and that Petitioner's laboratory director failed to provide "overall management and direction of the laboratory" based upon findings of violation of various standards for participation listed in the SOD. CMS Ex. 10, at 8; CMS Ex. 11, at 8.

The regulation at 42 C.F.R. § 493.1447 provides:

> Sec. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.
>
> The laboratory must have a technical supervisor who meets the qualification requirements of Sec. 493.1449 of this subpart and provides technical supervision in accordance with Sec. 493.1451 of this subpart.

Section 493.1451 sets forth the technical supervisor's responsibilities. The surveyors allege that the regulation was violated because Petitioner did not have a technical supervisor who provided technical oversight of the laboratory as evidenced by the facts that staff did not follow written quality control procedures, there was a lack of performance of verification procedures, staff was incompetent, proficiency testing was

not performed, and there was a lack of quality assessments – findings that were based upon various standard-level deficiency findings set forth in the SOD. CMS Ex. 10, at 13; CMS Ex. 11, at 13.

Petitioner was given an opportunity to correct the deficiencies and Petitioner submitted to CMS allegations of compliance and supporting evidence. However, CMS determined that Petitioner continued to have the condition-level deficiencies cited by the survey. CMS Exs. 2, 3, 11, and 12.

Petitioner does not dispute that it was not in compliance with the two condition-level requirements and the standard-level requirements cited during the July 21, 2008 survey. Request for Hearing at 7; P. Brief at 2. Rather, Petitioner argues that it applied for CLIA certification by mistake based on information provided by the state agency; that pursuant to 42 C.F.R. § 493.3(b)(2) it did not need a CLIA because it is "simply a research and development laboratory and did not perform tests on patient samples;" and that its CLIA certificate should have been terminated rather than suspended and revoked. Request for Hearing at 7, 8; P. Brief at 4-5. Petitioner admits that prior to the July 21, 2008 survey it tested seven human serum samples obtained from the Acacio Fertility Center. Request for Hearing at 7; P. Brief at 2-3.

The undisputed facts satisfy the CMS burden to make a prima facie showing of a violation of the two condition-level requirements established by 42 C.F.R. § 493.1441 and 42 C.F.R. § 493.1447. Petitioner has conceded that its laboratory was not in substantial compliance with the CLIA requirements. Accordingly, I conclude that CMS had a basis for the suspension and revocation of Petitioner's CLIA certificate.

7. Petitioner cannot avoid revocation of its CLIA certificate by withdrawal of its application or voluntary termination of its participation in CLIA.

8. Petitioner does not have a right to review on the issues of whether or not it was properly subject to CLIA or whether CMS should have permitted Petitioner to withdraw from participation in CLIA.

Petitioner argues that it is not subject to CLIA because it was purely a research and development laboratory and that its application should be treated as void or terminated rather than subject to suspension and revocation. Petitioner argues that its primary focus since 2006 has been the development of sHLA-G [serum histocompatibility antigen class G] testing principles for the determination of the level of secretion of sHLA-G in media surrounding individually cultured embryos for use as a marker to predict the capacity for implantations without rejection. Request for Hearing at 2; P. Ex. A. Based on the belief that it could further develop and perfect the theory of embryo well-being, Petitioner applied for CLIA certification in order to measure the concentration of sHLA-G proteins

in serum samples. Request for Hearing at 2. Petitioner points-out that it had previously been issued a CLIA certificate in July 2006, and on July 27, 2007 its CLIA certificate was simply terminated when Petitioner was found not ready for an initial CLIA inspection. Petitioner argues that the same result should have occurred with the CLIA certificate at issue before me. Request for Hearing at 2; P. Ex. B. Petitioner states that it applied for the second CLIA certificate after consultation with the state agency because a Czechoslovakian company had developed a kit that was commercially available that improved the sHLA-G testing procedure and therefore Petitioner believed that the procedure could be improved and test results would be more reliable if serum testing was performed. Request for Hearing at 3. In its January 19, 2009 letter to CMS, Petitioner clearly states that it initially intended to test human specimens and to offer the test for diagnostic purposes. Petitioner stated in its letter to CMS that "CARI has applied for CLIA certificate to have an option in the future to offer this test [the sHLA-G level in serum/plasma] as indicator for normal pregnancy." CMS Ex. 12, at 1. Petitioner also does not deny that it conducted tests on seven human specimens before allegedly abandoning the idea. CMS Ex. 12 at 1-2; CMS Ex.16, at 4.

CMS argues that it did not make any determination as to whether Petitioner needed a CLIA certificate. Rather, a CLIA certificate was issued to Petitioner based on Petitioner's application for a CLIA certificate and its representations in its application, specifically, Petitioner represented in its application that it intended to engage in diagnostic tests related to general immunology and that it expected to conduct 200 diagnostic tests per year in order to "diagnose complications of pregnancy." CMS Reply at 1; CMS Ex. 9, at 3 and 5. CMS argues that in Petitioner's January 18, 2008 application and during the application process, Petitioner did not represent itself as a "purely research laboratory." According to CMS, Petitioner is attempting to avoid the penalty of revocation, and it is trying to withdraw its application for a CLIA certification after receiving unfavorable survey results. CMS Brief at 7.

I am not persuaded by Petitioner's arguments. Petitioner applied for a CLIA certificate and when the certificate was issued, Petitioner was subject to survey or inspection and a variety of civil penalties for failing to comply with CLIA conditions for participation. 42 U.S.C. § 263a(g), (h), (i); s*ee also*, H.R. Rep. No. 100-899, 100th Cong. 2d Sess. 8, 18 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3839. The regulation is clear that a laboratory issued a registration certificate "must permit an initial inspection to assess the laboratory's compliance with the [CLIA] requirements . . ." and that "[t]he inspection may occur at any time during the laboratory's hours of operation." 42 C.F.R. § 493.1777(a)(1), (2). When Petitioner obtained a certificate of registration, it subjected itself to an initial certification survey by CMS or the state agency as CMS's agent. 42 C.F.R. §§ 403.1777(a)(2), 493.1773(a).

CMS argues that despite Petitioner's wish to withdraw its CLIA application, CMS is entitled to impose the revocation sanction against Petitioner as CMS is responsible to protect the public from Petitioner's owner and/or operator owning or operating another laboratory for a two-year period. CMS relies on two Board decisions to support its assertions, *HRT Laboratory Inc.*, DAB No. 2118, at 14 (2007); *Center Clinical Laboratory*, DAB No. 1526, at 11 (1995), *citing* 42 U.S.C. § 263a(i)(3). Both Board decisions support CMS's position. The Board's decision in *Rosewood Living Centre*, also supports the CMS position that a provider may not avoid a termination action imposed by CMS by "voluntarily" terminating its participation or withdrawing from the Medicare program, thereby avoiding the consequences of involuntary termination. *Rosewood Living Center*, DAB No. 2019 (2006), *citing Crescent Healthcare*, DAB No. 1888 (2003) (upholding CMS's right to terminate "without regard to any post-survey effort to effect a voluntary termination."). I find the Board's prior decisions persuasive. Petitioner cannot avoid revocation of its CLIA certificate by now claiming it was only conducting testing of human specimens purely for research purposes and by requesting voluntary withdrawal from CLIA or termination of its CLIA certificate. Furthermore, Petitioner's right to hearing before an ALJ is limited to the four initial determinations listed in 42 C.F.R. § 493.1844(b)(1).

9. CMS is not estopped from denying Petitioner's attempted withdrawal from CLIA and CMS is not estopped from suspension and revocation of Petitioner's CLIA certificate due to conduct of the state agency.

Petitioner argues that it was not knowledgeable as to CLIA requirements and Petitioner's owner was misled when advised by a state government employee that Petitioner needed to obtain a CLIA certificate. P. Brief at 3. Petitioner argues that it applied for and was issued a CLIA certificate on July 26, 2006. Petitioner alleges that during a July 23, 2007 survey of its laboratory, a state surveyor told one of Petitioner's owners that if the laboratory was not performing tests on human serum it did not need to be CLIA certified. P. Brief 1; Request for Hearing at 2. Petitioner subsequently received a letter from the state agency dated July 27, 2007 stating that its CLIA certificate was being terminated effective the date of application and instructing Petitioner: "[w]hen your laboratory is fully operational, you may contact our office again to reapply for CLIA certification and schedule the mandatory compliance survey at that time . . . ." P. Brief at 1; P. Ex. B at 1; CMS Ex. 8, at 3. Petitioner alleges that its owner subsequently contacted William Garrett at the state agency who advised Petitioner's owner that a CLIA certificate was required. P. Brief at 2. Petitioner argues that its owner was unfamiliar with the law and the procedures and did apply for a CLIA certificate that was issued on February 27, 2008. P. Brief at 2; CMS Ex. 9.

Petitioner's argument is that Mr. Garret and the surveyor should have known that Petitioner was not subject to CLIA and should have simply terminated Petitioner's CLIA certificate as was done in 2007. P. Brief at 5. Petitioner never specifically asserts that CMS is estopped from revoking Petitioner's CLIA certificate, but that is a possible interpretation of Petitioner's argument. The defense is without merit. Even if the state agency officials made the statements attributed to them by Petitioner and Petitioner's prior participation in CLIA was simply terminated, estoppel will not lie in this case. Based upon the facts alleged by Petitioner, it is clear that the state surveyor and her boss Mr. Garret, gave Petitioner's owner inconsistent advice as to whether or not a CLIA certificate was required. Petitioner cannot argue in the face of such inconsistency that it acted reasonably based upon the advice of either state official. Furthermore, assuming for the sake of discussion that one or both state officials were wrong in their interpretation of CLIA, I do not find CMS bound or equitably estopped. *Heckler v. Cmty. Health Srvs. of Crawford County*, 467 U.S. 51, 63 (1984); *Office of Personnel Management v. Richmond*, 496 U.S. 414 (1990). The Board has relied on *Heckler* for the proposition that when a party has knowledge of the truth, or had means by which with reasonable diligence he could acquire the knowledge so that it would be negligence on his part to remain ignorant by not using those means, he cannot claim to have been misled by relying on the representation or concealment. *Wade Pediatrics*, DAB No. 2153 (2008), at 24-25 (2008), *aff'd*, 567 F3d 1202 (10th Cir. 2009) (*citing* 467 U.S. 51 at 61, n.10). The statute and implementing regulations unambiguously set forth the requirements for CLIA certification. Petitioner's asserted ignorance is no excuse and no basis for upsetting revocation of its CLIA certificate. Accordingly, I will not interfere with the CMS action based on a theory of estoppel.

III. Conclusion

Based on the foregoing, I conclude that there was a basis for revocation of Petitioner's CLIA certificate and it is revoked effective the date of this decision.

/s/
Keith W. Sickendick
Administrative Law Judge