Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

The Malaria & Rheumatic Disease Research Institute, Inc.
(CLIA No.: 21D2065315),

Petitioner,

v.

Centers for Medicare & Medicaid Services,

Respondent.

Docket No. C-16-200

Decision No. CR4918

Date: August 14, 2017

DECISION

The Centers for Medicare & Medicaid Services (CMS) determined that The Malaria & Rheumatic Disease Research Institute, Inc. (Petitioner or MARDRI) did not comply with a condition for laboratories under the Clinical Laboratory Improvement Act (CLIA) and imposed the principal sanctions of suspension of Petitioner's CLIA certificate and cancellation of Petitioner's approval to receive Medicare reimbursements for its services. Later, CMS revoked Petitioner's CLIA certificate and imposed an immediate suspension, citing Petitioner's refusal to allow state surveyors to inspect its laboratory. Petitioner requested hearings to dispute both the suspension and revocation of its CLIA certificate. For the reasons explained below, I affirm CMS's suspension and revocation of Petitioner's CLIA certificate.

I. Applicable Law

In order to ensure the accuracy and reliability of laboratory tests, and thus the health and safety of those tested, CLIA creates a federal certification process for laboratories that

perform clinical diagnostic tests on human specimens. Public Law No. 100-578, *amending* section 353 of the Public Health Service Act, codified at 42 U.S.C. § 263a *et seq.*; *see* H.R. Rep. No. 100-899, at 8, *reprinted in* 1988 U.S.C.C.A.N. 3828, 3829. To be certified, a laboratory must meet the conditions of certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1); 42 C.F.R. Part 493. A condition represents a major division of laboratory services or required environmental protections; each condition is broken down into more detailed standards that laboratories must meet to be compliant with the overall condition. *White Lake Family Med., P.C.*, DAB No. 1951 at 2 (2004); *RNA Labs.*, DAB No. 1820 at 1 (2002).

The statute gives the Secretary of Health and Human Services (Secretary) broad enforcement authority, which the Secretary has delegated to CMS. CMS or its designee conducts periodic inspections to determine a laboratory's compliance with CLIA requirements. 42 C.F.R. § 493.1777. CMS may 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 (e.g., directed plan of correction, state monitoring, and/or civil money penalty). 42 C.F.R. § 493.1806; *White Lake*, DAB No. 1951 at 7. "Failure by a laboratory to comply with even a single condition in an area of testing offered by that laboratory may be grounds for suspension or revocation of a laboratory's CLIA certificate." *RNA Labs.*, DAB No. 1820 at 2, *citing Ward Gen. Practice Clinic*, DAB No. 1624 at 2 (1997). Noncompliance with even one standard, if sufficiently serious, may justify a condition-level deficiency. *Edison Med. Labs., Inc.*, DAB No. 1713 at 1-2 (1999).

II. Background and Procedural History

Overview

Petitioner is a laboratory that operated under a CLIA certificate issued by CMS. During the period of September 2013 through December 2014, state surveyors found deficiencies at Petitioner's laboratory, and attempted to bring Petitioner into compliance with CLIA. After these efforts ultimately failed, the state survey agency referred Petitioner's case to CMS. In March 2015, CMS issued an initial determination and imposed the alternative sanction of a directed plan of correction. In April 2015, CMS imposed principal sanctions of suspension of Petitioner's CLIA certificate and cancellation of Petitioner's approval to receive Medicare payments. In June 2015, Petitioner filed a first request for hearing; Petitioner submitted what state surveyors deemed to be a credible allegation of compliance, and the surveyors scheduled a revisit to verify that allegation. From July 2015 through August 2015, CMS attempted to schedule and perform a revisit of Petitioner's laboratory to verify its compliance. After surveyors were unable to conduct a revisit survey in August 2015, CMS notified Petitioner that it was imposing principal sanctions, which included revocation and immediate suspension of Petitioner's CLIA

certificate in November. In December 2015, Petitioner filed a second request for hearing. I consolidated Petitioner's two cases and held a hearing in June 2016.

The State Survey Process

On September 9, 2013, CMS provided Petitioner with a CLIA certification of registration, which permitted Petitioner to start operating. CMS Exhibit (Ex.) 7 at 1; CMS Ex. 38 ¶ 9; CMS Ex. 40 at 1. Starting December 2013, Gail McGucken, a surveyor with the Maryland Department of Health and Mental Hygiene (state survey agency), attempted to schedule a survey at Petitioner's facility to ensure that Petitioner met the conditions for CLIA certification. CMS Ex. 38 ¶¶ 1, 6. After some difficulty scheduling the survey, Ms. McGucken ultimately conducted the survey in two visits, on March 21, 2014, and April 29, 2014. CMS Ex. 38 ¶¶ 12-22; *see also* CMS Ex. 29 at 1. On April 29, 2014, she was assisted by surveyor Martin Tate. CMS Ex. 36 ¶ 6.

Based on the survey, the surveyors concluded that Petitioner had two condition-level CLIA deficiencies. On May 8, 2014, Ms. McGucken spoke to the Laboratory Director for Petitioner, Millicent Coker-Vann, Ph.D., and informed her of the survey findings. CMS Ex. 38 ¶ 42; CMS Ex. 40 at 1.

In a May 13, 2014 notice, the state survey agency formally informed Dr. Coker-Vann that Petitioner failed to meet the following conditions:

> **D5400 – 42 C.F.R. § 493.1250 Condition: Analytic systems;**
> **D6076 – 42 C.F.R. § 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.**

CMS Ex. 4 at 1-2 (emphasis in original). Included with the form was a detailed Statement of Deficiencies (CMS-2567). CMS Ex. 1. The notice further informed Dr. Coker-Vann that:

> Laboratories that do not meet the Condition-level requirements of CLIA may not be certified to perform laboratory testing under the CLIA program. You must take steps to bring any unmet Conditions into compliance immediately.
>
> You are directed to submit a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited. Please document your allegation of

> compliance[1] using the enclosed CMS-2567, Statement of Deficiencies, in columns labeled "Provider Plan of Correction" and "Completion Date" located on the right side of the form . . . . The laboratory director must sign, date and return the completed CMS-2567 documented with a credible allegation of compliance with our office WITHIN 10 DAYS FROM RECEIPT of this notice.

CMS Ex. 4.

Petitioner did not respond to the state survey agency's notice until June 11, 2014, but only after Ms. McGucken tried to contact Dr. Coker-Vann several times and the state survey agency gave Petitioner a ten-day extension of time. CMS Ex. 29 at 1, 3; CMS Ex. 32; CMS Ex. 38 ¶¶ 43-44. Following receipt of Petitioner's response (CMS Ex. 5), the surveyors reviewed it and determined that it was not only confusing and inadequate, but included "a new preparation log for the Bentonite Flocculation (BF) test, transcribed the old date on to a new worksheet, added a new line for sodium azide, and printed it on [Petitioner's] letterhead. (*Compare* CMS Ex. 5 at 5 *to* CMS Ex. 28 at 4). It is not appropriate to re-create a preparation log long after the preparation took place." CMS Ex. 38 ¶¶ 44-45.

In a June 25, 2014 notice, the state survey agency informed Dr. Coker-Vann that Petitioner's response to its previous notice "does not constitute a credible allegation of compliance and acceptable evidence of correction." CMS Ex. 6 at 1. The notice provided a detailed explanation for the state survey agency's decision and gave Petitioner ten days to submit a credible allegation of compliance and acceptable evidence of correction. CMS Ex. 6 at 2-5. The notice informed Petitioner that a failure to make an acceptable submission could result in various principal sanctions (suspension, limitation and/or revocation of CLIA certificate) or alternative sanctions (directed plan of correction, civil money penalties and/or onsite monitoring by the state). CMS Ex. 6 at 4-5.

Ms. McGucken attempted to contact Dr. Coker-Vann regarding the need to submit a new allegation of compliance, and eventually spoke to her on July 9, 2014, more than 10 days after she gave notice that the laboratory's last submission did not suffice. On July 15,

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[1] "*Credible allegation of compliance* means a statement or documentation that—(1) Is made by a representative of a laboratory that has a history of having maintained a commitment to compliance and of taking corrective action when required; (2) Is realistic in terms of its being possible to accomplish the required corrective action between the date of the exit conference and the date of the allegation; and (3) Indicates that the problem has been resolved." 42 C.F.R. § 493.2 (definition of credible allegation of compliance).

2014, Dr. Coker-Vann informed the state survey agency that Petitioner was suspending laboratory testing because she had been in a car accident. CMS Ex. 7 at 2; CMS Ex. 31 at 2; CMS Ex. 38 ¶¶ 45-47. Because the state survey agency had not received a response to its letter from June, the state survey agency sent Dr. Coker-Vann a letter on September 2, 2014, stating that if Petitioner did not submit an acceptable plan of correction, Petitioner's CLIA certificate might be terminated. CMS Ex. 7 at 2; CMS Ex. 38 ¶ 48.

The state survey agency received submissions from Dr. Coker-Vann on September 24, 2014 and September 29, 2014; however, Dr. Coker-Vann apparently meant for the September 29 submission to supersede the September 24 one. CMS Ex. 8; CMS Ex. 38 ¶ 48. The surveyors reviewed the September 29 submission and found that it not only failed to make a credible allegation of compliance, but failed to include records to show Petitioner verified its equipment. CMS Ex. 38 ¶¶ 49-50. On October 3, 2014, Ms. McGucken called and spoke to Dr. Coker-Vann about the requirements for a credible allegation of compliance and stated that the state survey agency would send a letter again giving Petitioner ten more days to respond. CMS Ex. 29 at 8; CMS Ex. 38 ¶ 50. The state survey agency sent that letter on October 15, 2014. CMS Ex. 9. The letter described in detail the deficiencies involved in this matter and stated that if the state survey agency did not receive a credible allegation of compliance and acceptable evidence of correction, it would forward the case to CMS with recommendations for sanctions. CMS Ex. 9 at 2-4. The letter warned, "[o]nce your case has been referred, the CMS Regional Office has final authority for any sanction to be imposed and will inform you of its determination and appeals procedures." CMS Ex. 9 at 5.

Petitioner did not respond to the October 15, 2014 letter and, on December 2, 2014, the state survey agency referred Petitioner's matter to CMS. CMS Ex. 10; CMS Ex. 38 ¶ 52.

CMS Initial Determination and Sanctions

After the state survey agency referred Petitioner's case to CMS, CMS assigned medical technologist Kimberly Weaver to process the enforcement action. CMS Ex. 37 ¶ 8. In a January 21, 2015 letter, CMS notified Petitioner that it intended to impose various principal and alternative sanctions if Petitioner did not return to compliance. CMS Ex. 11; CMS Ex. 40 at 2. On February 10, 2015, CMS received a response from Petitioner, which included what CMS deemed to be a credible allegation of compliance with respect to only the Analytic Systems condition; CMS concluded that Petitioner had failed to submit a credible allegation of compliance for the Laboratory Director condition. CMS Ex. 37 ¶¶ 15-16. On February 11, 2015, CMS notified Petitioner that it would defer imposing any sanctions while it reviewed Petitioner's submission. CMS Exs. 12-14.

In a March 4, 2015 initial determination, CMS decided to impose the alternative sanction of a directed plan of correction. CMS imposed this alternative sanction based on a continued deficiency for: "42 C.F.R. § 1441 Condition: Laboratory Director." CMS

warned that a failure to comply with the directed plan of correction could result in CMS imposing principal sanctions on Petitioner. CMS also notified Petitioner that it could request a hearing before an administrative law judge (ALJ) to dispute the imposition of an alternate sanction. CMS Ex. 15; CMS Ex. 40 at 2.

On April 7, 2015, CMS issued an initial determination imposing principal sanctions on Petitioner, effective June 10, 2015, because Petitioner continued to have a condition level deficiency and Petitioner failed to respond to CMS's directed plan of correction. CMS imposed a suspension of Petitioner's CLIA certificate and cancellation of Petitioner's approval to receive Medicare payments. CMS provided Petitioner with notice of its right to request a hearing before an ALJ. CMS Ex. 16.

On May 7, 2015, CMS received a submission from Dr. Coker-Vann indicating that she had been out of the country and could not respond to CMS's earlier notices in a timely manner. The submission included a number of documents related to the substance of CMS's notices. CMS Ex. 17.

In a letter dated May 11, 2015, CMS acknowledged receipt of Dr. Coker-Vann's submission and indicated that CMS had reviewed it. However, CMS determined that the submission did "not constitute a credible allegation of compliance and [did] not comply with the requirements of the directed plan of correction." CMS stated that the principal sanctions would become effective on June 10, 2015, unless Petitioner filed a request for hearing. CMS Ex. 18; CMS Ex. 37 ¶ 8.

Petitioner's First Request for Hearing

On June 2, 2015, Petitioner filed a request for hearing, dated May 29, 2015. The case was docketed as case number C-15-2773 by the Civil Remedies Division and assigned to me for hearing.

Also on June 2, 2015, CMS received another submission from Petitioner. CMS Ex. 19. While the surveyor for the state survey agency noted that Petitioner "sent documents that did not appear to be responsive to CMS's requests," she determined that Petitioner "had finally submitted what I deemed to be a credible allegation of compliance on all tags[.]" The state survey agency scheduled a revisit for July 31, 2015. CMS Ex. 37 ¶¶ 31, 32; CMS Ex. 40 at 2.

On July 2, 2015, I issued an Acknowledgment and Pre-Hearing Order. In response to that order CMS submitted Exhibits 1-38 and Petitioner submitted one exhibit. Three of CMS's exhibits were written direct testimony for witnesses. CMS Exs. 36-38.

Attempted Revisits by the State Survey Agency

On July 28, 2015, the state survey agency telephoned Petitioner to announce a revisit survey of its laboratory on July 31, 2015. During that call, Petitioner's laboratory director told the state survey agency that she was under the impression that surveyors should not visit the laboratory while it was under suspension and Petitioner was appealing that suspension. CMS Ex. 20 at 1; CMS Ex. 40 at 2.

On August 4, 2015, CMS sent a letter to Petitioner summarizing the telephone discussion of July 28, 2015, and informing Petitioner that "its agents are authorized to inspect the laboratory, and inform you of the consequences of refusing a survey." CMS Ex. 20 at 1. CMS's letter also noted that Petitioner's appeal had stayed the suspension, but that CMS could issue a suspension prior to a hearing if Petitioner refused a survey. CMS Ex. 20 at 2. The letter notified Petitioner that CMS had scheduled a visit for August 25, 2015. CMS Ex. 20 at 2.

CMS received a letter from Petitioner on August 18, 2015, in which Petitioner stated that it had retained an attorney to assist it with the matter, and that CMS should direct all correspondence to its attorney. CMS Ex. 21.

On August 24, 2015, Petitioner's counsel emailed CMS's counsel, ultimately confirming that Petitioner's laboratory director would be present for the survey visit scheduled for the following day, August 25, 2015 at 10:00 a.m. Petitioner's counsel clarified that the laboratory director's reason for initially stating that she would be unavailable was because "she had guests from out of the country." Petitioner also conveyed through counsel that "the stress of prior CMS visits were of concern to her due to her current understaffing and health and the amount of work required during past visits." CMS Ex. 26 at 1.

On August 25, 2015, just after midnight, at 12:18 a.m., Petitioner's laboratory director visited a hospital emergency room complaining of a headache, dizziness, and blurred vision. CMS Ex. 34 at 2. The hospital release form contains a date stamp for "08/25/2015 03:27:35" but also states that the patient was seen on "8/24/15," the provider's signature is dated August 24, 2015, and states that the patient "[m]ay return to work / school without restrictions on 8/26/15." CMS Ex. 34 at 1.

The state surveyors arrived at Petitioner's laboratory at 10:00 a.m. for the scheduled inspection, and nobody was present. CMS Ex. 37 ¶ 35. Unbeknownst to them, that same morning, at 9:46 a.m., Petitioner had emailed her attorney to relay to CMS that she would not be present for the inspection scheduled for 10:00 a.m. Petitioner's counsel forwarded that email to CMS counsel at 12:31 p.m. CMS Ex. 27 at 2.

On November 24, 2015, CMS notified Petitioner that it was imposing principal sanctions, which included revocation and immediate suspension of Petitioner's CLIA certificate. CMS Ex. 40.

Petitioner's Second Request for Hearing

On December 23, 2015, Petitioner filed a second request for hearing, docketed as C-16-200, appealing the principal sanctions imposed. On January 21, 2016, I issued a consolidation order, consolidating C-15-2773 and C-16-200. CMS filed a pre-hearing brief (CMS Pre. Br.) and CMS Ex. 39. Petitioner filed a pre-hearing brief (P. Pre. Br.) and two proposed exhibits (P. Exs. 1-2), [2] but neither of these exhibits included the written direct testimony for any witnesses. Petitioner requested to cross-examine CMS's witnesses.

I held an in-person hearing on June 28, 2016. Hearing Transcript (Tr.) at 1. During the hearing I heard testimony from all three of CMS's witnesses: Kimberly Weaver, Gail McGucken, and Martin Tate. Prior to the hearing, I admitted all of CMS's Exhibits 1 through 39, and both of Petitioner's Exhibits 1 and 2. At the hearing, I admitted CMS's revised Exhibits 5 and 12, as well as CMS's Exhibit 40, all of which were unopposed by Petitioner. Tr. at 8-9. After the hearing, CMS and Petitioner filed post-hearing briefs (CMS Post. Br. and P. Post. Br.); CMS and Petitioner filed replies to the post-hearing briefs (CMS Reply, P. Reply).

III. Jurisdiction

I have jurisdiction in this matter pursuant to 42 C.F.R. § 493.1844(a)(2), (b)(1).

IV. Issues

The issues in this case are:

1. Whether Petitioner failed to comply with the Laboratory Director condition required for Petitioner's participation in CLIA;
2. Whether Petitioner refused to permit CMS to conduct a survey of its laboratory; and

[2] Petitioner submitted CMS's letter of November 24, 2015, the originating case decision along with its request for hearing, and its filename contains the label "P. Ex. 1," but this is not what Petitioner later submitted as its first exhibit (a letter from Petitioner notifying me that it intended to retain counsel). The originating case decision was later submitted by CMS as CMS Ex. 40.

3. Whether CMS legitimately imposed sanctions, including suspension prior to an ALJ hearing, during Petitioner's pending appeal.

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

My findings of fact and conclusions of law are in bold and italicized text.

1. Petitioner failed to comply with the Laboratory Director condition required for Petitioner's participation in CLIA.

CMS has the burden to present sufficient evidence to make a *prima facie* case supporting its allegations. Thereafter, Petitioner has the burden to prove by a preponderance of the evidence that it was in compliance, thus rebutting CMS's *prima facie* case. *Alaa Ahmed, M.Sc., Ph.D. Global Esoteric Reference Labs, Inc.*, DAB No. 1878 at 5 (2003) *citing Edison Med. Labs., Inc*., DAB No. 1713 (1999), *aff'd*, *Edison Med. Labs., Inc., v. Thompson*, 250 F.3d 735 (3rd Cir. 2001); *see also Hillman Rehab. Ctr.*, DAB No. 1611 (1997), *aff'd*, *Hillman Rehab. Ctr. v. United States*, No. 98-3789 (GEB) (D.N.J. May 13, 1999).

CMS presented evidence supporting Petitioner's condition-level deficiency for failure to meet the Laboratory Director condition (Tag D6076)[3]. CMS Ex. 1 at 16; CMS Post. Br. at 3. The Laboratory Director condition states that a "laboratory must have a director who meets the qualification requirements of § 493.1443 of this subpart and provides overall management and direction in accordance with § 493.1445 of this subpart." 42 C.F.R. § 493.1441. CMS alleges that Petitioner did not comply with this condition because its laboratory director failed to fulfill four out of 15 responsibilities enumerated in 42 C.F.R. § 1445(e):

- 42 C.F.R. § 493.1445(e)(1) (Tag D6082): the laboratory director must ensure that testing systems provide quality laboratory services for all aspects of test performance;

[3] Tag D6076: "This tag is a condition-level deficiency related to the duties of the laboratory director of a high-complexity laboratory. MARDRI is classified as a high-complexity laboratory. One reason for that classification is that MARDRI manufactures the majority of its solutions itself, unlike other labs which purchase the solutions they use to perform tests. There are more stringent education and experience requirements for MARDRI's Laboratory Director as compared to the Laboratory Director of a moderate-complexity laboratory." CMS Ex. 38 at 7 ¶ 24.

- 42 C.F.R. § 493.1445(e)(3)(ii) (Tag D6086): the laboratory director must ensure that the laboratory's verification procedures used are adequate to determine the accuracy and precision of its test methodologies;
- 42 C.F.R. § 493.1445(e)(4) (Tag D6088): the laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program; and
- 42 C.F.R. § 493.1445(e)(15) (Tag D6107): the laboratory director must specify, in writing, the responsibilities and duties of each consultant, supervisor, and each person engaged in the performance of preanalytic, analytic, and postanalytic phases of testing.

CMS Ex. 1 at 16-21.

As explained in detail below, I conclude that CMS has presented sufficient evidence to support a prima facie case that Petitioner failed to meet no less than three of the enumerated standards listed above, resulting in Petitioner's failure to meet the entire Laboratory Director condition. *See Edison Med. Labs., Inc.*, DAB No. 1713 at 1-2 (1999) (summarizing the interrelationship between conditions and standards, and indicating that "noncompliance with one or more particular standards relating to a condition may or may not be serious enough to cause a deficiency at the level of the condition."). Petitioner has presented little to no evidence to rebut CMS's case. Petitioner's main arguments that it made a good faith effort or a credible, but unverified allegation of compliance, are legally insufficient. In other words, "trying one's best" does not suffice under CLIA, and cannot be the baseline upon which to establish a regime of accurately and reliably testing human specimens.

I will discuss the first three standards in turn, but for reasons of judicial economy, I will omit discussion of the last standard.

1.a. Petitioner was not in compliance with 42 C.F.R. § 1445(e)(1) (Tag D6082), because Petitioner's laboratory director failed to ensure that its testing systems provided quality laboratory services.

CMS alleges that Petitioner's laboratory director failed to ensure that its testing systems provided quality laboratory services as required under 42 C.F.R. § 1445(e)(1) and that Petitioner failed to dispute CMS's findings in this proceeding. CMS Post. Br. at 3-4. Petitioner challenges this allegation by stating that it made a good faith effort to comply with the requirement, and also claims that the state survey agency had stated that Petitioner had made a "credible allegation of compliance." P. Post. Br. at 11. I find that CMS has presented sufficient evidence of noncompliance, which Petitioner has failed to rebut.

According to 42 C.F.R. § 1445(e)(1), "[t]he laboratory director must (1) [e]nsure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing . . . ."

In the Statement of Deficiencies on Form CMS-2567, the state surveyors found that: (1) "the laboratory director could not find the operator's manual" for several laboratory instruments, including centrifuges and pipettes; (2) records lacked entries for initial validations of equipment; and (3) pipette calibration worksheets did not indicate when they were calibrated and lacked corresponding identification numbers. CMS Ex. 1 at 17.

Petitioner responded to the state surveyor's first finding, in its Plan of Correction, that it had manuals in its possession, but "key employees" were not present at the survey, and the laboratory director had difficulty finding manuals:

> For other new employees in training, the laboratory Director was not aware that some manuals had been moved as such they were not seen when the surveyor made a first visit because the trainee was not present. The microscope manual was in the desk on which the microscope was sitting. By the second visit, the other manuals had been moved back to a bookshelf in the laboratory to facilitate easy retrieval.

CMS Ex. 1 at 17.

Next, Petitioner responded to the state surveyor's second finding that the laboratory records did not contain a date for initial validation by simply confirming that the equipment had been validated prior to testing, but did not provide any dates. In response to the third finding concerning pipette calibration worksheets, Petitioner seems to argue that validation had occurred at a predecessor laboratory:

> Validation of equipment prior to testing had been done for over 10 years at the Arthritis Research Center laboratory and the process was not changed because a new organization was started. The process may have been incomplete because inexperienced employees were in training which sometimes takes a long [time] to complete. . . . The correct worksheet was not reviewed by the surveyors.[4]

[4] Petitioner's laboratory director also stated that she had previously served as a director at the Arthritis Research Center, and thus seems to argue that because the equipment had been previously validated at that laboratory it should apply to Petitioner, without any explanation as to why such previous validation should still apply to a new entity. CMS Ex. 5 at 1.

CMS Ex. 1 at 17.

Most of Petitioner's responses seem to indicate that most of its equipment documentation existed within the laboratory at the time of the survey, so it invites the question as to why its director could not locate, or the surveyors did not review, the relevant documents at the time of the survey. The written direct testimony of one surveyor provides some context:

> I arrived at MARDRI at 9:30 am on March 21st. The laboratory director met me at the door, and took me on a tour of the rooms where testing was to be performed. I noticed that the laboratory was cluttered. Papers were in piles, and laboratory equipment and materials were crowded on the counter tops rather than being stored in an organized fashion. I started to review the data that was available. I was repeatedly unable to find the documentation I needed to review, such as worksheets documenting how tests had been performed and what results were obtained, and records showing that the laboratory equipment were appropriate for use. This is basic laboratory documentation that I expect to be readily available, especially for an announced survey.

CMS Ex. 38 ¶ 16.

The surveyor further testified that when she requested documentation from Petitioner's laboratory director, she would wait for up to ten minutes until the director returned with documents that often did not address her inquiry. She spent three hours during her initial visit, and then consulted another surveyor regarding the state of Petitioner's documentation. The other surveyor agreed that the state of Petitioner's documentation "was confusing and agreed to come with me to complete the survey . . . In my 24 years of surveying, there have been only a handful of times I have had to ask a second surveyor to help me complete a survey which had been scheduled for one surveyor." CMS Ex. 38 ¶¶ 17-18, 21.

The surveyor also testified that Petitioner could not demonstrate validation and proficient use of certain key laboratory equipment such as pipettes, a centrifuge, and a refrigerator thermometer:

> MARDRI did not demonstrate that each of its pipettes dispensed the precise amount of liquid it was marked as dispensing. Without that information, MARDRI did not know if the pipettes were dispensing more or less solution than they should. Discrepancies in the amount could cause inaccurate results. When I asked Dr. Coker-Vann for

> documentation that the pipettes were validated, she showed me a calibration worksheet dated "1/XX/10" that included the serial numbers of six pipettes. (CMS Ex. 28 at 2). I reported on the 2567 that none of those numbers matched the numbers on the pipettes the laboratory had in use in April 2014.
>
> …
>
> MARDRI failed to show that it had validated the centrifuge to make sure it was working at the proper speed. Failure to spin the liquid at the prescribed speed can prevent particles from separating from the liquid, and can distort test results.
>
> …
>
> MARDRI did not ensure that the thermometer used to monitor the temperature of the refrigerator and freezer it uses to store patient samples, reagents and solutions was valid. If these items are not stored at the proper temperature, their integrity can be compromised, again causing the laboratory to produce inaccurate results.

CMS Ex. 38 ¶¶ 27-29.

Petitioner does not dispute the findings of surveyors that its documentation was in disarray. Rather, Petitioner argues that it *made a good faith effort to demonstrate substantial compliance* with this requirement. P. Pre. Br. at 12-13. Petitioner highlights that, by the second visit, some previously missing equipment manuals were in order and accessible. [5] P. Pre. Br. at 13.

Finally, Petitioner claims that since it "has made a credible allegation of compliance on all tags" it "should have its CLIA certificate and Medicare payments reinstated." P. Post. Br. at 11. It argues that it should not be sanctioned since it "has submitted multiple reports to CMS in an effort to evidence compliance with CLIA regulations." P. Post. Br. at 11. On June 2, 2015, CMS received one such submission. CMS Ex. 19; CMS Ex. 37 ¶ 30. After reviewing this submission, a state surveyor determined that the information contained therein, combined with other documents provided in prior submissions, constituted "a credible allegation of compliance on all tags." CMS Ex. 37 ¶¶ 30, 32.

[5] In its Pre-Hearing Brief at 13, Petitioner refers to CMS Ex. 5 at 20, Petitioner's letter dated June 5, 2014, which simply refers back to its Plan of Correction in CMS Ex. 1 at 16, where it states that it had calibrated equipment prior to patient testing without providing dates – which is unresponsive to the allegation that its documentation lacked dates verifying when the validation occurred.

I find Petitioner's arguments that it is compliant with CLIA because it has made a good faith effort to comply with the regulations, or alternatively that it has made a credible allegation of compliance, unconvincing. First, a good faith effort to comply with regulations established to ensure public safety is not the appropriate standard for me to apply in this case. Nowhere does Petitioner cite any law that establishes a good faith compliance standard. The regulation at 42 C.F.R. § 1445(e)(1) states that a laboratory director "must ensure" that testing systems provide quality laboratory services – not simply put forth a good faith effort.

Second, after a CLIA laboratory makes a credible allegation of compliance, then CMS or its agent must review that allegation, and if necessary, schedule a visit to verify compliance. 42 C.F.R. § 493.1810(e). Despite numerous attempts by the state survey agency to schedule a visit for the purpose of verifying Petitioner's compliance, such visit (and verification) never occurred. Moreover, while the regulations allow CMS the discretion to impose alternative sanctions prior to imposing principal sanctions of suspension or revocation, CMS's decision to impose alternative sanctions does not alter the fact that Petitioner was not, in fact, in compliance at the time of the survey.

I find that CMS has made a *prima facie* case by submitting credible evidence of deficiencies in Petitioner's laboratory director's responsibility to ensure that the laboratory had developed testing systems to provide quality laboratory services. Petitioner's arguments that it made a good faith effort or a credible, but unverified allegation of compliance, do not establish sufficient evidence to rebut CMS's case.

1.b. Petitioner was not in compliance with 42 C.F.R. § 493.1445(e)(3)(ii) (Tag D6086), because Petitioner's laboratory director failed to ensure that Petitioner had procedures for verifying, and actually verified, its testing systems.

CMS alleges that Petitioner has failed to show that its laboratory director ensured that it had procedures for verifying, and actually verified, its testing systems as required under 42 C.F.R. § 1445(e)(3)(ii). CMS Post. Br. at 4. CMS argues that Petitioner failed to meet subsection (ii) of the following regulation:

> The laboratory director must [e]nsure that [t]he test methodologies selected have the capability of providing the quality of results required for patient care; (ii) [v]erification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and (iii) [l]aboratory personnel are performing the test methods as required for accurate and reliable results[.]

42 C.F.R. § 493.1445(e)(3).

Petitioner responds to CMS's position by stating that it "made a good faith effort to demonstrate substantial compliance" by providing documentation in its hearing request and plan of correction describing its verification procedures. P. Pre. Br. at 4.

The state surveyors found that Petitioner could not produce laboratory records that included verification procedures and validation for certain tests performed at the laboratory, including Rheumatoid Factor, Mycoplasma Antibody titer, Mycoplasma Antigen, Kunkel y-Globulin, Antistreptolysin O (ASO) titer, and Chlamydia antibodies. CMS Ex. 1 at 18. One of the state surveyors testified as to the importance of verification in ensuring that CLIA laboratories can obtain and document test results "within the established minimum standards" prior to patient testing as required by regulation. CMS Ex. 38 ¶ 31; *see* 42 C.F.R. § 493.1253. Testing standards can come from test kit manufacturers or a laboratory itself, if it manufactures its own test kit. The state surveyor stated that Petitioner did manufacture "many test kits it uses" and therefore she would have expected Petitioner to maintain procedures that "instruct the technician on how to verify each test." CMS Ex. 38 ¶ 32. She found neither verification procedures in Petitioner's procedure manual, nor any record of testing verification during her visit to Petitioner's laboratory. CMS Ex. 38 ¶ 33.

Petitioner, in its Plan of Correction, stated that "verification for tests performed using test kits verification of the validity of these tests had been provided by the kit manufacturers in their protocols and not repeated at MARDRI, i.e. ASO and Chlamydia pneumonia." CMS Ex. 1 at 18. This assertion seems to fall short of compliance with the objective, since the goal of the standard is to ensure that the laboratory verify the tests in its own environment to make sure that it could accurately and precisely perform tests on human samples. Yet, Petitioner explicitly stated that the verification had not been repeated, and the only explanation that Petitioner offers for not repeating the verification is that verification had already been performed by Petitioner's laboratory director when she previously served as laboratory director at another laboratory. CMS Ex. 1 at 18; P. Pre. Br. at 14. Petitioner argues that, analogous to its previous argument regarding equipment validation, CMS should accept its testing verification that occurred at the Arthritis Research Center between 2002 and 2009. CMS Ex. 5 at 52-59. It does not explain how or why CMS should accept those testing results from years prior at a different laboratory.

Petitioner stated that it had also performed tests using in-house procedures (for test kits that it manufactures itself), and that a log of such validation testing existed. However, once again Petitioner claimed that, "unfortunately the wrong sheet was reviewed" by the surveyor. CMS Ex. 1 at 18. I found no evidence in the record that Petitioner provided the correct sheet to surveyors. This argument again reinforces the state surveyor's testimony (referenced in the previous section) regarding the chaotic state of Petitioner's laboratory records, and does not provide any assurance that Petitioner could reliably perform and maintain accurate records of testing on human samples.

I find that Petitioner was not in compliance with 42 C.F.R. § 493.1445(e)(3)(ii), because Petitioner's laboratory director failed to ensure that it had procedures for verifying, and actually verified, its testing systems. Petitioner's submission of records of previous verifications from another laboratory, years prior the events in this case, does not meet this standard. Again, for reasons already discussed in the previous section, I find Petitioner's arguments that it made a good faith effort to demonstrate substantial compliance and that it had made a credible allegation of compliance unavailing.

1.c. Petitioner was not in compliance with 42 C.F.R. § 493.1445(e)(4) (Tag D6088), because Petitioner's laboratory director failed to ensure that Petitioner was enrolled in proficiency testing.

CMS alleges that Petitioner's laboratory director failed to ensure that Petitioner was enrolled in proficiency testing. Petitioner admits that it was not enrolled in proficiency testing for one type of test. CMS Ex. 1 at 19. Petitioner also argues that it "made a good faith effort to demonstrate substantial compliance" by including various documentation with its request for hearing including certificates of participation in testing programs offered by trade associations, and other testing schedules and materials. P. Pre. Br. at 15. While CMS disputes the validity of the certificates of the testing programs that Petitioner submitted, it is not necessary to discuss their validity, since Petitioner admitted that it had not established a proficiency testing program for Chlamydia.

Proficiency testing is an important part of CLIA. "Each laboratory holding a CLIA certificate to do tests of moderate and/or high complexity must participate in a proficiency testing (PT) program that is approved by CMS[.]" *White Lake*, DAB No. 1951 at 2. The statute establishing CLIA mandated that the Secretary establish a proficiency testing program:

> The Secretary shall establish standards for the proficiency testing programs for laboratories issued a certificate under this section which are conducted by the Secretary. . . . The standards shall require that a laboratory issued a certificate under this section be tested for each examination and procedure conducted within a category of examinations or procedures for which it has received a certificate, except for examinations and procedures for which the Secretary has determined that a proficiency test cannot reasonably be developed. The testing shall be conducted on a quarterly basis, except where the Secretary determines for technical and scientific reasons that a particular examination or procedure may be tested less frequently (but not less often than twice per year).

42 U.S.C. § 263a(f)(3)(A).

The regulation at 42 C.F.R. § 493.1445(e)(4) states that a CLIA laboratory director must:

> Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that—
> (i) The proficiency testing samples are tested as required under subpart H of this part;
> (ii) The results are returned within the timeframes established by the proficiency testing program;
> (iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and
> (iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory[.]

The state surveyors found that Petitioner had not enrolled in proficiency testing: (i) prior to commencing operations in September 2013; and (ii) for Chlamydia at the time of the survey in March and April 2014. CMS Ex. 1 at 19; CMS Post. Br. at 6. Petitioner admitted in its Plan of Correction that it was not enrolled in proficiency testing for Chlamydia. CMS Ex. 1 at 19.

"The laboratory 'must successfully participate' in an approved PT program for each 'specialty, subspecialty, and analyte or test in which it is certified under CLIA.' 42 C.F.R. § 493.803(a)." *White Lake*, DAB No. 1951 at 2. Since Petitioner had not successfully participated in an approved proficiency testing program for Chlamydia, a test which it had performed, it was not in compliance with this required standard.

2. CMS appropriately applied sanctions, including immediate suspension prior to an ALJ hearing during Petitioner's pending appeal.

This second issue regards the appropriateness of the remedies sought by CMS.

CMS applied both alternative and principal sanctions for Petitioner's failure to comply with the laboratory director condition. The alternative sanction was a directed plan of correction. Thereafter, CMS moved forward with principal sanctions of suspension of Petitioner's CLIA certificate, cancellation of Petitioner's approval to receive Medicare payments. Finally, after state surveyors were unsuccessful in their attempts to verify Petitioner's compliance, CMS imposed an immediate suspension, prior to an ALJ hearing, and revocation of Petitioner's CLIA certificate based on Petitioner's refusal to allow state surveyors to conduct an inspection of Petitioner's laboratory to verify Petitioner's allegation of compliance. Petitioner argues that it did not refuse the state surveyors' inspection, and, therefore, its CLIA certificate should not have been immediately, or thereafter, suspended.

As explained in the previous section, I find that Petitioner did not comply with the laboratory director condition. That finding formed a basis to impose the principal sanctions of suspension and cancellation of Petitioner's CLIA certificate under 42 C.F.R. § 493.1814(a)(2). However, failure to comply with a condition alone does not provide grounds for an *immediate* suspension. CMS argues that it was authorized pursuant to 42 C.F.R. § 493.1840 to immediately suspend, and subsequently revoke, Petitioner's CLIA certificate because Petitioner refused a request to inspect its laboratory. Therefore, I must separately review whether Petitioner refused an inspection request – and whether CMS correctly imposed immediate suspension and revocation.

2.a. Petitioner's failure to comply with the laboratory director condition provided a basis for CMS to impose the principal sanctions of suspension under 42 C.F.R. § 493.1814(a)(2), and cancellation of approval to receive Medicare payments pursuant to 42 C.F.R. § 493.1808(a).

CMS acted within its scope of authority to suspend Petitioner's CLIA certificate because Petitioner failed to fulfill the laboratory director condition. Based on 42 C.F.R. § 493.1808(a), it follows automatically that CMS may also cancel Petitioner's approval to receive Medical payments once it suspends the CLIA certificate. The regulations do not require CMS to provide laboratories with the opportunity to correct any condition level deficiencies, even if they do not pose immediate jeopardy.

The enforcement procedures of the CLIA regulations serve the purpose of protecting people "against the substandard testing," "safeguarding the general public against health and safety hazards," and "[t]o motivate laboratories to comply with CLIA requirements." 42 C.F.R. § 493.1804(a). The enforcement mechanisms for achieving these purposes include alternative and principal sanctions. 42 C.F.R. § 493.1806. CMS may decide to impose sanctions when CMS or its agents conduct laboratory inspections and discover deficiencies or find "unsuccessful participation in proficiency testing." 42 C.F.R. § 493.1804(b)(1). CMS may consider 9 factors when choosing which sanction to impose. 42 C.F.R. § 493.1804(d). Those 9 factors include "whether the deficiencies pose immediate jeopardy," "the nature, incidence, severity, and duration of the deficiencies or noncompliance," and "the overall compliance history of the laboratory including but not limited to any period of noncompliance that occurred between certifications of compliance."

The three principal sanctions under CLIA "are suspension, limitation, or revocation of any type of CLIA certificate." 42 C.F.R. § 493.1806(b). Alternative sanctions include a "directed plan of correction," among others. 42 C.F.R. § 493.1806(c). "CMS may impose alternative sanctions in lieu of, or in addition to principal sanctions . . . ." 42 C.F.R. § 493.1804(c)(1). Upon the suspension or revocation of a CLIA certificate,

"CMS concurrently cancels the laboratory's approval to receive Medicare payment for its services." 42 C.F.R. § 493.1808(a).

"CMS may suspend, limit, or revoke [a] laboratory's CLIA certificate" when a "laboratory has condition level deficiencies that do not pose immediate jeopardy." 42 C.F.R. § 493.1814(a)(2).

As soon as CMS or its agent discovers failure to meet a condition, a basis exists for imposing a suspension, limitation or revocation. *See id*. Therefore, as long as CMS has proven the existence of a condition level deficiency at any point in time since the laboratory began operating under a CLIA certificate, CMS was authorized to impose the principal sanction of suspension or revocation. As a result, I only need determine compliance at the time of the survey, and Petitioner's other efforts to return to compliance are irrelevant.

Petitioner confuses the lifting of alternative sanctions under 42 C.F.R. § 493.1810(e) – which states that when there is a credible allegation of compliance, and CMS or its agent conducts a revisit of the laboratory, it may lift alternative sanctions – with the rules related to principal sanctions. However, CMS or its agent deeming Petitioner's submission as a credible allegation of compliance does not vitiate CMS's right to impose principal sanctions such as suspension. Further, the state survey agency determined that it needed to conduct a revisit, which never occurred, so the credible allegation of compliance was never verified.

I conclude that CMS had a basis for suspending Petitioner's CLIA certificate for failure to comply with the laboratory director condition. However, CMS may not impose an *immediate* suspension for Petitioner's failure to comply with a condition that does not pose an immediate jeopardy. *See* 42 C.F.R. § 493.1840(d)(2). Therefore, I must also examine whether CMS had a basis to impose an immediate suspension for refusing an inspection under 42 C.F.R. § 493.1840(a)(5).

2.b. CMS had a basis for imposing an immediate suspension and the subsequent revocation under 42 C.F.R. § 493.1840 because Petitioner refused a request to inspect its laboratory.

I now examine whether CMS had the authority under 42 C.F.R. § 493.1840 to impose immediate suspension prior to an ALJ hearing and subsequent revocation for refusing an inspection. CMS argues that it was authorized to immediately suspend and revoke Petitioner's CLIA certificate in November 2015 because Petitioner's laboratory director refused state surveyors when they came to inspect its laboratory, and, more generally, that Petitioner engaged in a pattern of conduct over an extended period of time that obstructed state surveyors from completing an inspection of Petitioner's laboratory.

Petitioner argues that inaction by its laboratory director, due to medical emergency, cannot be construed as a refusal.

CMS may impose "suspension, limitation, or revocation of any type of CLIA certificate" if "CMS finds that a laboratory's owner or operator or one of its employees has– [r]efused a reasonable request by CMS or its agent for permission to inspect the laboratory and its operation and pertinent records during hours that the laboratory is in operation[.]" 42 C.F.R. § 493.1840(a)(5). Therefore, this provision is comprised of three elements: (1) a reasonable request, (2) during working hours of operation, and (3) refusal of a request to inspect.

As far as timing of a suspension is concerned, CMS generally may not impose a suspension or limitation of a CLIA certificate prior to an ALJ decision affirming CMS's decision to impose such sanctions. 42 C.F.R. § 493.1840(d)(1). However, there are exceptions to the rule prohibiting suspension prior to ALJ review. CMS "may suspend or limit a CLIA certificate before the ALJ hearing" when "the laboratory has refused permission for CMS or a CMS agent to inspect the laboratory or its operation." 42 C.F.R. § 493.1840(d)(2)(iii).

With regards to the timing of a revocation, CMS may not "revoke any type of CLIA certificate until after an ALJ hearing that upholds revocation." 42 C.F.R. § 493.1840(e).

CMS argues that it was authorized to immediately suspend and subsequently revoke Petitioner's CLIA certificate in November 2015 because the three elements required for a sustainable action under 42 C.F.R. § 493.1840(a)(5) applied: (1) CMS's request was entirely reasonable, especially given the context that Petitioner had been operating for over two years without conclusively demonstrating that its laboratory was in compliance with CLIA; (2) the inspection was scheduled and attempted during Petitioner's ordinary hours of operation, as it was scheduled for a Tuesday, on August 25, 2015 at 10:00 a.m.; and (3) Petitioner refused the inspection." CMS Post. Br. at 9; P. Post. Br. at 1; CMS Ex. 38 at 16.

The third element, whether Petitioner refused the inspection, is the only one in contention. During the hearing, Petitioner's counsel cross-examined CMS's three witnesses, the state surveyors who conducted the inspection. Petitioner's counsel focused the scope of cross-examination solely on the issue of refusal. *See* Tr. CMS argues that Petitioner need not affirmatively state its refusal, by saying "no" to inspectors. CMS Post. Br. at 13-14. It argues that Petitioner refused the inspection by not being present at the scheduled time to open its laboratory to inspectors. "Petitioner's failure to notify CMS, or even her own attorney, between 3:30 am and 9:46 am on the day of the inspection evidences her mental determination not to comply with CMS's request to inspect the laboratory." CMS Post. Br. at 14.

Petitioner argues that it "did not refuse a reasonable request to inspect the laboratory because it took no affirmative action to refuse the request, and the request was not reasonable." P. Post. Br. at 4. Petitioner cites a definition of refusal in Black's Law Dictionary as the "denial or rejection of something offered or demanded." P. Post. Br. at 5. Here, Black's Law Dictionary can only serve as a persuasive source, but not an authoritative legal precedent, and therefore, I am not bound by that definition.

Both Petitioner and CMS only refer to one Departmental Appeals Board (DAB) decision to support their opposing positions: *US Bio-Chem Medical Laboratories, Inc*., DAB No. 1731 (2000). That case dealt with a refusal to inspect under a different section of the same subpart, but also pertained to a refusal.

In *US Bio-Chem*, the DAB addressed a laboratory's refusal in the context of CMS's right to inspect and found that such right was unconditional, but it did not define refusal. *US Bio-Chem*, DAB No. 1731 at 2. In *US Bio-Chem*, during the inspection of a CLIA laboratory triggered by a complaint, inspectors requested that laboratory employees produce a patient log book. The laboratory's president interrupted the inspection, demanding to know the identity of the complainant, and refused to produce the log book. *Id.* at 1. The petitioner in that case argued that it had a Constitutional right to know the identity of the complainant prior to the inspection. The DAB reasoned:

> The key problem with these arguments is that they assume that the right to know the complainant, if established, would also establish that Bio-Chem had the right to refuse to produce the log book and that [CMS's] remedies were unauthorized. As the ALJ concluded, however, the right to inspect is unconditional and Bio-Chem could not reasonably refuse to produce the log book based on the inspectors' failure to disclose the complainant at that time.

Id. at 2.

In this case, Petitioner distinguishes its own behavior from those exhibited in *US Bio-Chem*. Petitioner notes that the refusal in *US Bio-Chem* was unequivocal and clear, since Bio-Chem's president spoke directly to inspectors; in other words, the refusal was based on an affirmative action. CMS argues that such an interpretation of a refusal would be too limited, and would allow a laboratory to "evade an inspection simply by being closed on the day of the inspection." CMS Post. Br. at 14.

I conclude that the surveyors' request to inspect Petitioner's laboratory was entirely reasonable, and during normal business hours. CMS needed to verify Petitioner's credible allegation of compliance, which seemed to be incredibly difficult to do. CMS scheduled and rescheduled its visits to accommodate Petitioner; it would appear that a laboratory in full compliance would be eager to schedule a visit as soon as possible in

order to maintain its status as a CLIA laboratory. On the contrary, rather than proceed expeditiously, Petitioner's laboratory director told state surveyors on July 28, 2015, in response to an effort to schedule an inspection on July 31, 2015, that she was under the impression that surveyors should not visit the laboratory while it was under suspension and Petitioner was appealing that suspension. CMS Ex. 20 at 1; CMS Ex. 40 at 2. After the state survey agency rescheduled, she then stated that she had to entertain international guests. In light of CMS's and the state surveyors' extensive communications with Petitioner and Petitioner's counsel, and the duration of time during which Petitioner had operated without a "clean bill of health," this inspection was entirely reasonable and necessary.

Finally, I conclude, looking at the unique facts and circumstances present in this case, that Petitioner's conduct, even in the absence of an affirmative action, constitutes refusal. Petitioner has not cited any binding authority defining refusal as an affirmative act; *US Bio-Chem* does not support Petitioner's position, as it does not define refusal. Limiting the interpretation of what constitutes a "refusal" to an affirmative action results in too constrained a definition, and could lead to abusive practices by laboratories to evade and obstruct inspection.

CMS not only argues that Petitioner refused the inspection attempted on August 25, 2015, but also that one must view that singular occurrence as part of a larger pattern of obstruction by Petitioner:

> This case is also about a lab that for a period of 15 months failed to timely respond to CMS's requests for information, failed to submit complete responses, failed to return phone calls and failed to pick up certified mail from CMS and the state agency. Finally, in August 2015, the lab [director] failed to appear for a scheduled and announced revisit and did not inform the surveyors beforehand that the lab [director] would not be present.

Tr. at 15, lines 6-14.

In essence, CMS argues that Petitioner's laboratory director's pattern of behavior that culminated in her failure to receive state survey inspectors on August 25, 2015, constituted a refusal. [6]

The Secretary possesses broad statutory authority to inspect laboratories under CLIA. "The Secretary has the right to conduct inspections on an announced or unannounced

[6] CMS's letter to Petitioner, dated November 24, 2015, summarizes most of the procedural history documenting the back and forth between Petitioner and both CMS and state survey agency. CMS Ex. 40.

basis, enter and inspect, during regular hours of operation, laboratories which have been issued a certificate under this section." 42 U.S.C. § 263a(g)(1). Despite the existence of that broad authority to conduct inspections, I can find no statutory or regulatory guidance explicitly defining refusal under CLIA. Given the paucity of case law interpreting refusal of inspections under CLIA, it is worth examining the experience of the Food and Drug Administration (FDA) in conducting analogous inspections, as that agency has a longer experience with the issue of refusal and the rights of entities to refuse inspections has been more extensively litigated in that context.[7] The FDA, like CMS, is an agency within the Department of Health and Human Services, and its conduct of inspections to regulate food and drug safety is quite similar to that of CMS's role in inspecting laboratories under CLIA. While the FDA's guidance does not govern or create binding precedent for me to follow, it does provide some persuasive authority on how another agency within HHS interprets refusals of inspections.

Refusal of an FDA inspection under 21 U.S.C. § 331(f) is a criminal offense. According to the FDA's final guidance published in 2014, various conduct can be interpreted as a refusal, including:

> • *delays in scheduling a preannounced inspection*;
> • delays during an inspection;
> • delays in producing records, including hardcopy and electronic records, files and papers;
> • denials of inspections (such as, among other examples, when a facility that sends its staff home for the day and tells the FDA investigator that the facility is not producing any product);
> • *refusals to permit entry or inspection, which the FDA interprets to include "not only active, but also passive behavior and nonaction by the owner, operator, or agent of a drug facility.*"

FDA Enforcement Manual ¶ 350 (emphasis added).[8]

Petitioner has engaged in behavior that corresponds to those described in the bullets above. Petitioner delayed scheduling a preannounced inspection, and it provided

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[7] The FDA's long history of inspections led to federal court decisions, including the Supreme Court's decision in the *United States v. Cardiff*, 344 U.S. 174, 73 S.Ct. 189 (1952), and *United States v. Thriftimart, Inc*. 429 F.2d 1006 (1970).

[8] The availability of the final agency guidance was announced in an Oct. 22, 2014 Federal Register notice (79 Fed. Reg. 63130). *See* https://www.federalregister.gov/documents/2014/10/22/2014-25033/guidance-for-industry-on-circumstances-that-constitute-delaying-denying-limiting-or-refusing-a-drug; https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM360484.pdf

numerous excuses as to why it could not conduct the revisit. Petitioner's actions also seem to constitute passive behavior as described in the last bullet above. One of the state surveyors testified that Petitioner's laboratory director's "actions, specifically her lack of cooperation regarding the revisits, her absence from the lab on August 25th, her difficulty and delay in submitting a credible allegation of compliance, and the many unreturned phone calls and failed faxes beginning in December 2013, had consumed an extraordinary amount of the surveyors' time." CMS Ex. 37 at 11.

I conclude that CMS had a basis for the immediate suspension and subsequent revocation of Petitioner's CLIA certificate.

VI. Conclusion

For the reasons explained above, I affirm CMS's suspension and revocation of Petitioner's CLIA certificate, as well as cancellation of Petitioner's approval to receive Medicare reimbursements for its services.

/s/
Scott Anderson
Administrative Law Judge