

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division**

The Malaria & Rheumatic Disease Research Institute, Inc.
Docket No. A-18-6
Decision No. 2872
May 28, 2018

**FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION**

The Malaria & Rheumatic Disease Research Institute, Inc., (Petitioner, MARDRI, the laboratory), requests review of the August 14, 2017 decision of an Administrative Law Judge (ALJ), *The Malaria & Rheumatic Disease Research Institute, Inc.*, DAB No. CR4918 (ALJ Decision). The ALJ upheld the imposition of an immediate suspension and, ultimately, revocation by the Centers for Medicare & Medicaid Services (CMS) of MARDRI's certificate of registration to operate as a clinical laboratory. CMS based its suspension and revocation determinations on MARDRI's non-compliance with certain certification standards and conditions and its refusal to allow the state surveyors to inspect its laboratory. For reasons we explain below, we affirm the ALJ's decision.

Legal Authorities

The Social Security Act provides that any laboratory services paid for under a state medical assistance plan must be provided by a laboratory which meets the Secretary's requirements, state licensing requirements and the certification requirements under § 353 of the Public Health Service Act. *See* 42 U.S.C. 1395x; §§1861(e)(9); 1861(s)(16), (17).

The Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a *et seq.*, and the implementing regulations at 42 C.F.R. Part 493, establish conditions that laboratories must meet to be certified to perform clinical diagnostic testing on human specimens and to bill for services under the Medicare program. *See* 42 C.F.R. § 493.1. Congress enacted CLIA to ensure that the results of tests are reliable and accurate. H.R. Rep. No. 899, 100th Cong., 2nd Sess. 8 (1988). The Secretary of the Department of Health and Human Services (HHS) administers CLIA, through CMS.

Per § 493.2, "CLIA certificate" includes, as relevant here, the following type of certificates issued by CMS or its agent:

[A] [c]*ertificate of registration or registration certificate* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with § 493.45, that enables the entity to conduct moderate or high complexity laboratory testing or both until the entity is determined to be in compliance through a survey by CMS or its agent; or in accordance with § 493.57 to an entity that is accredited by an approved accreditation organization.

In order to maintain its CLIA certification, a laboratory must meet the conditions of certification set out in the statute and regulations. In general, a laboratory performing clinical diagnostic testing is not in compliance with CLIA requirements unless it has one of the certificates specified in the regulations (such as a registration certificate). 42 C.F.R. §§ 493.3, 493.5(c). Requirements for laboratories holding a registration certificate include submitting to inspection by HHS and demonstrating compliance with the applicable requirements of subparts H, J, K, M, and Q of the regulations. § 493.45(c)(2), (3). The registration certificate is valid until a compliance inspection is completed or up to two years (whichever is shorter). § 493.45(e). Although it cannot be renewed, the certificate can be reissued if HHS has not determined compliance prior to its expiration. *Id.*

Each certification condition represents a general requirement for the laboratory to meet, and the standards set out under the conditions constitute their specific components. *Victor Valley Cmty. Hosp./Clinical Lab., et al.*, DAB No. 2340, at 2 (2010) and the cases cited therein. Noncompliance with one or more individual standards relating to a condition may be serious enough to cause a condition level deficiency. *See* 42 C.F.R. §§ 493.2, 493.1812-16; 57 Fed. Reg. 7218, 7219 (Feb. 28, 1992).

Subpart K of the implementing regulations establishes the Quality System for Nonwaived Testing, which requires, among other things, “written policies and procedures to implement a quality system for all phases of the total testing process”; a quality assessment component that “ensures continuous performance improvement” via ongoing monitoring to identify, evaluate and resolve problems; and that quality system components are used to meet the regulatory requirements of Part 493 and are “appropriate for the laboratory’s testing specialties and subspecialties, the services it offers, and the clients it serves.” § 493.1200(a)-(c).

Among the requirements of Part 493 applicable to the laboratory subject of this appeal are:

§ 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.

The 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.

* * *

§ 493.1445 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.

* * *

(e) The laboratory director must—

(1) Ensure 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;

* * *

(3) Ensure that—

* * *

(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

* * *

(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed . . .

* * *

(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

Pursuant to 42 C.F.R. § 493.1804(b)(2), when CMS finds that a laboratory has condition level deficiencies, as defined at 42 C.F.R. § 493.2, “CMS imposes one or more of the alternative or principal sanctions specified in §§ 493.1806 and 493.1807” *See also* 42 C.F.R. § 493.1806(a). A condition level deficiency is defined as “noncompliance with one or more condition level requirements,” that is, any of the requirements identified as conditions in subparts H through Q of Part 493. 42 C.F.R. § 493.2.

Failure to comply with even a single applicable condition is a ground for CMS to impose one or more principal or alternative sanctions. 42 C.F.R. § 493.1806(a); *Ward Gen. Practice Clinic*, DAB No. 1624, at 2 (1997). Principal sanctions include suspension, limitation, or revocation of a laboratory’s CLIA certificate. 42 C.F.R. § 493.1806(b). Alternative sanctions include directed plans of correction, state on-site monitoring, and civil money penalties. 42 C.F.R. § 493.1806(c).

Under § 493.1810, CMS may impose alternative sanctions on a laboratory for condition level noncompliance. CMS will not lift alternative sanctions until a laboratory’s compliance with all condition level requirements is verified, either through credible allegations of compliance supported by evidence presented by the laboratory in its allegation, or through a revisit, during which CMS verifies whether the laboratory has in fact achieved compliance. § 493.1810(e)(2).

If a laboratory has condition level deficiencies that do not pose immediate jeopardy, CMS may 1) cancel the laboratory’s approval to receive Medicare payment for its services; and 2) suspend, limit, or revoke the laboratory’s CLIA certificate. § 493.1814.

The action CMS takes if a survey finds that a laboratory is not in compliance with the requirements depends in part on (1) whether the deficiencies are only at the level of one or more standards or rise to the level of noncompliance with one or more conditions and (2) whether the deficiencies pose an immediate jeopardy. 42 C.F.R. §§ 493.1812 to 493.1816. Where none of the deficiencies are condition level deficiencies, the laboratory must submit a plan of correction and show on revisit that it has corrected the deficiencies. 42 C.F.R. § 493.1816; *Edison Med. Labs.*, DAB No. 1713, at 2 (1999), *aff’d*, *Edison Med. Lab. v. Thompson*, 250 F.3d 735 (3rd Cir. 2001).

CMS or the state survey agency may visit the laboratory at any time to evaluate progress and to determine whether all corrections to deficiencies in CLIA certification compliance have been made. § 493.1820(a).

CMS may suspend payment for all Medicare-approved laboratory services when the laboratory has condition level deficiencies. § 493.1828(a). CMS may also impose a directed plan of correction as an alternative sanction for any laboratory that has condition level deficiencies. § 493.1832(a).

CMS may initiate adverse action to suspend, limit or revoke any CLIA certificate if CMS finds that a laboratory's owner or operator or one of its employees has, among other things, "[r]efused a reasonable request by CMS or its agent^[1] for permission to inspect the laboratory and its operation and pertinent records during the hours that the laboratory is in operation[.]" § 493.1840(a)(5).

Generally, CMS does not suspend or limit a CLIA certificate until after an ALJ hearing decision that upholds suspension or limitation, except that "CMS may suspend or limit a CLIA certificate" where "[t]he laboratory has refused permission for CMS or a CMS agent to inspect the laboratory or its operation." § 493.1840(d)(2)(iii).

Section 493.1844(f), captioned "*Appeal rights of laboratories,*" provides in part:

(1) *ALJ hearing.* Any laboratory dissatisfied with the suspension, limitation, or revocation of its CLIA certificate, with the imposition of an alternative sanction under this subpart, or with cancellation of the approval to receive Medicare payment for its services, is entitled to a hearing before an ALJ as specified in paragraph (a)(2) of this section and has 60 days from the notice of sanction to request a hearing.

Section 493.1844(a)(2) states that hearings "are conducted in accordance with procedures set forth in subpart D of part 498 of this chapter"

Standard of review

The standard of review on a disputed factual issue is whether the ALJ decision is supported by substantial evidence in the record as a whole. The Board's standard of review on a disputed issue of law is whether the ALJ decision is erroneous. *Guidelines – Appellate Review of Decisions of Administrative Law Judges in Cases Under the Clinical*

¹ "CMS agent" means an entity with which CMS arranges to inspect laboratories and assess laboratory activities against CLIA requirements and may be a State survey agency, a private, non-profit organization other than an approved accreditation organization, a component of HHS, or any other governmental component CMS approves for this purpose. 42 C.F.R. § 493.2.

Laboratory Improvement Amendments of 1988 (CLIA) and Related Statutes, accessible at <http://www.hhs.gov/dab/divisions/appellate/guidelines/clia.html>.

Case Background²

Petitioner is a laboratory which obtained a CLIA certificate of registration in September 2013. CMS Ex. 38, at 3 ¶ 9. The laboratory director is Millicent Coker-Vann, Ph.D. *Id.* at 10; *see also* CMS Ex. 37. Petitioner is classified as a high-complexity laboratory. CMS Ex. 38, at 7 ¶ 24.

Three months after receiving its registration certification, G.M., a surveyor with the Maryland Department of Health and Mental Hygiene, the state survey agency, attempted to schedule a survey at the laboratory to ensure that Petitioner met the conditions for CLIA certification. ALJ Decision at 3; CMS Ex. 38, at 4 ¶ 12. G.M. was unable to reach Petitioner by telephone in December 2013. *Id.* In January 2014, G.M. was able to reach Petitioner, but Petitioner claimed that the laboratory had just began testing, implying that a survey was premature. *Id.* at 4 ¶¶ 13. Ultimately, G.M. scheduled the survey visit for March 21, 2014. *Id.* at 4-5 ¶¶ 15; *see also* CMS Ex. 29, at 1.

During the initial survey, G.M. observed that the director had difficulty locating essential documentation with which to respond to G.M.'s questions because the laboratory appeared disordered. CMS Ex. 38, at 5 ¶¶ 16-18. G.M. also noted that the director produced non-responsive documents. ALJ Decision at 12; CMS Ex. 38, at 5 ¶ 18. G.M. returned on April 29, 2014 to complete the survey, accompanied by fellow surveyor, M.T. CMS Ex. 38, at 6 ¶¶ 19-22. The state agency found two separate condition level CLIA deficiencies: (1) 42 C.F.R. § 493.1250, "Analytic systems"; and (2) 42 C.F.R. § 493.1441, "Laboratories performing high complexity testing; laboratory director" (hereinafter "Laboratory Director condition"). The laboratory did not meet eighteen standards. ALJ Decision at 3.

On May 13, 2014, the state survey agency notified Petitioner of the laboratory's deficiencies with a form CMS 2567 (Statement of Deficiencies). *Id.*; CMS Ex. 4. The state survey agency letter informed Petitioner:

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.

² The information in this section is drawn from the undisputed facts in the ALJ Decision and in the record before the ALJ.

CMS Ex. 4, at 2. The letter further notified Petitioner that Petitioner had 10 days to submit a credible allegation of compliance,³ and that failure to do so could result in sanctions. *Id.* at 2-3. The state survey agency further informed Petitioner that the agency could conduct an on-site revisit within 30 to 45 days. CMS Ex. 38, at 12 ¶ 42.

Petitioner failed to respond timely to the notice. *Id.* at 12 ¶ 43. G.M. made several fruitless attempts to contact Petitioner from June 3, 2014 through June 10, 2014. *See id.* The state survey agency issued another letter to the Petitioner on June 5, 2014, providing a 10-day extension for Petitioner to submit “a credible allegation of compliance and acceptable evidence of correction.” CMS Ex. 32; ALJ Decision at 4. On June 11, 2014, G.M. received a response from Petitioner. CMS Ex. 38, at 12-13 ¶ 44.

The state survey agency determined that Petitioner’s submission did not constitute a credible allegation of compliance and acceptable evidence of correction, rejecting it as “confusing” and “inadequate,” in part, because it included at least one document which appeared to have been altered after the initial survey and re-submitted with Petitioner’s response. ALJ Decision at 4 (citing CMS Exs. 5, 28; 38, at 13 ¶ 44-45). Nonetheless, although the state surveyors notified the director that it had rejected Petitioner’s response to its previous notice, by letter dated June 25, 2014, the state survey agency provided Petitioner a third 10-day opportunity to submit a credible allegation of compliance and acceptable evidence of correction. CMS Ex. 6, at 2-5. The letter notified Petitioner of the need to make an acceptable submission and the possible sanctions for failure to do so. *Id.* at 4; ALJ Decision at 4.

Petitioner again failed to submit a credible allegation of compliance and acceptable evidence of correction. Yet, by letter dated September 2, 2014, the state survey agency afforded Petitioner a fourth opportunity to comply. ALJ Decision at 5; CMS Ex. 7. However, the state survey agency notified Petitioner that, if the state agency did not receive an acceptable plan of correction by September 23, 2014, Petitioner’s CLIA certificate might be terminated. *Id.*; CMS Ex. 38, at 14 ¶ 48. Petitioner submitted a response on September 24, 2014; and then another on September 29, 2014, indicating that Petitioner wished the state survey agency to disregard the September 24, 2014 submission. ALJ Decision at 5; CMS Ex. 38, at 14 ¶ 48. G.M. reviewed the September 29, 2014 submission and found that it failed to make a credible allegation of compliance, at least in part because it omitted records demonstrating that Petitioner had verified either its equipment or its test systems. CMS Ex. 38, at 14 ¶ 49; ALJ Decision at 5.

³ Section 493.2 of the regulations defines a credible allegation of compliance.

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.

G.M.'s colleague, M.T., also reviewed this submission and concurred that it was not a credible allegation of compliance. CMS Ex. 38, at 14-15 ¶ 50. After discussing the matter with M.T. and a supervisor, G.M. called Petitioner and spoke with the director to ensure that the director understood what was required, per the state survey agency's June 26, 2014 letter, for a credible allegation of compliance. *Id.* On October 15, 2014, the state survey agency sent a letter to Petitioner describing the information the agency required from Petitioner for a credible allegation of compliance. *See* CMS Ex. 9. In the letter, the state agency notified Petitioner that, if it did not receive a credible allegation of compliance, it would forward the case to CMS with recommendations for sanctions. *Id.* at 4-5. Petitioner failed to respond either to that letter or to a follow-up telephone call from M.T. to the director. CMS Ex. 10; CMS Ex. 38, at 15 ¶ 52. On December 2, 2014, the state survey agency notified Petitioner that the state agency had referred the matter to CMS for a sanctions determination. *Id.*

CMS assigned medical technologist K.W. to process the enforcement action. ALJ Decision at 5. On January 21, 2015, CMS sent a letter notifying Petitioner that CMS concurred with the state survey agency's determination that Petitioner was not in compliance with the Laboratory Director condition or the Analytic Systems condition. CMS Ex. 11, at 2. CMS also notified Petitioner that, if it failed to demonstrate compliance within 10 days, CMS would impose a directed Plan of Correction, effective in 15 days. *Id.* at 1, 6. In an effort to assist Petitioner, CMS attached to its letter a scaled-down version of a directed Plan of Correction, which required submission of only a minimally credible allegation of compliance. CMS Ex. 37, at 3 ¶ 10. If Petitioner satisfied these minimal requirements, the state survey agency would conduct a revisit to determine whether the facility was in compliance with CLIA requirements. However, if Petitioner failed to demonstrate compliance, CMS would suspend Petitioner's CLIA certificate. *Id.*

On February 10, 2015, Petitioner responded to CMS. ALJ Decision at 5. On February 11, 2015, CMS notified Petitioner that it had concluded that Petitioner had submitted what CMS deemed a credible allegation of compliance relating to the Analytic Systems condition, but not to the Laboratory Director condition; however, CMS elected to defer imposition of any sanction while it further reviewed Petitioner's submission. *Id.* (citing CMS Ex. 37, at 5-6 ¶¶ 15-16, *and* CMS Exs. 12-14). On March 4, 2015, CMS notified Petitioner of its initial determination to impose a directed Plan of Correction, an alternative sanction, because Petitioner failed to comply with the Laboratory Director condition. ALJ Decision at 5. If Petitioner failed to comply with the directed Plan of Correction, CMS could impose principal sanctions (including suspension of Petitioner's CLIA certificate). *Id.* at 5-6.

On April 7, 2015, CMS suspended Petitioner's CLIA certificate, effective June 10, 2015, based on its failure to comply with the Laboratory Director condition, and its failure to comply with the directed Plan of Correction. ALJ Decision at 6. CMS also cancelled

Petitioner's approval to receive Medicare payment for tests it performed. *Id.* CMS notified Petitioner of its right to request a hearing before an ALJ. *Id.* On May 7, 2015, Petitioner notified CMS that its director had failed to respond timely to CMS because she was out of the country, and it also submitted several documents purporting to respond to CMS's notices. *Id.* On May 11, 2015, CMS determined that Petitioner's submissions did not constitute a credible allegation of compliance or comply with the requirements of the directed Plan of Correction, and that, therefore, principal sanctions would take effect on June 10, 2015, unless Petitioner filed a request for ALJ hearing. *Id.*

On June 2, 2015, Petitioner appealed the suspension, and separately submitted additional documents to CMS. ALJ Decision at 6. After Petitioner filed its appeal, K.W. reviewed Petitioner's submission for CMS and, although some of the records appeared to be non-responsive, K.W. deemed these documents, together with other records Petitioner had previously submitted, a credible allegation of compliance on all of the conditions cited. CMS Ex. 37, at 9, ¶¶ 30-32; ALJ Decision at 6. K.W. then contacted the state survey agency to schedule a revisit. *Id.*

On July 28, 2015, the state survey agency contacted Petitioner to announce a revisit on July 31, 2015. ALJ Decision at 7. However, Petitioner's director objected to the revisit, citing Petitioner's current suspension and pending appeal. *Id.* (citing CMS Ex. 20, at 1; CMS Ex. 40, at 2). By letter dated August 4, 2015, CMS notified Petitioner that Petitioner's appeal had stayed the suspension, that CMS had determined that a revisit was necessary to verify compliance with the Laboratory Director condition, and that, under the regulations, CMS or its agents were authorized to visit the laboratory "at any time" to determine whether "all corrections ha[d] been made." CMS Ex. 20. CMS announced that it would survey Petitioner's laboratory on August 25, 2015. *Id.* Finally, CMS warned Petitioner's director that failure to appear for the visit would constitute failure to permit inspection, which would subject Petitioner to immediate suspension of its CLIA certificate, notwithstanding Petitioner's pending ALJ appeal, and would constitute the basis for the HHS Inspector General to exclude Petitioner from participation in all Federal and State health care programs. *Id.* at 2.

On August 24, 2015, Petitioner's newly retained legal counsel emailed CMS counsel to confirm that Petitioner's director would be present for the scheduled revisit on August 25, 2015, notwithstanding a previous statement from the director that she would be unavailable to attend the revisit. CMS Ex. 26. Her legal counsel attributed this earlier statement of unavailability to the impending visit of foreign guests and work-related stress resulting from understaffing. *Id.*; ALJ Decision at 7. However, the director did not appear at the appointed time (10:00 a.m.) for the August 25, 2015 revisit. ALJ Decision at 7. The state surveyors appeared at the laboratory but were unable to conduct the revisit. CMS Ex. 38, at 16 ¶55. Although the director had informed her legal counsel (shortly before the survey was to begin) that she would not be present, her counsel was unable to notify CMS counsel until past noon on the day of the scheduled revisit. ALJ

Decision at 7; CMS Ex. 27. Later that day, the director informed CMS that she had been at a hospital's emergency department overnight and that she had been advised to stay home from work for one day (the day of the revisit) and to return to work the following day with no restrictions. CMS Ex. 34.

CMS determined that Petitioner's failure to appear, or have someone present for the August 25, 2015 revisit, constituted a refusal to permit inspection. CMS Ex. 40. Therefore, on November 24, 2015, CMS suspended the laboratory's CLIA certificate immediately and revoked it pending an ALJ hearing, effective 15 days from the date of the letter. *Id.* On December 23, 2015, Petitioner filed a second request for ALJ hearing.

The ALJ Decision

The ALJ consolidated Petitioner's appeals⁴ and held an evidentiary hearing, taking live testimony from three CMS witnesses. ALJ Decision at 8. In addition, the ALJ reviewed the parties' written arguments, as well as more than 40 evidentiary exhibits comprising nearly 600 pages, including: the written testimony of the CMS witnesses; the state surveyors' survey notes; months of correspondence between Petitioner, the state survey agency, and CMS; and more than 11 submissions from Petitioner to the state survey agency and to CMS.⁵ After considering the evidence and the arguments of the parties, the ALJ concluded, in sum, that (1) Petitioner failed to comply with the Laboratory Director condition because its director did not prove compliance with the quality and proficiency testing standards listed at subsections 493.1445(e)(1), (e)(3)(ii), and (e)(4); and (2) CMS appropriately applied sanctions, including immediate suspension during Petitioner's pending appeal, because (in addition to failing to comply with the above-listed Laboratory Director condition) Petitioner refused a request to inspect Petitioner's laboratory. ALJ Decision at 9-19.

On appeal to the Board, Petitioner questions (1) whether substantial evidence supports the ALJ's findings that Petitioner failed to meet CLIA certification standards in the regulation at 42 C.F.R. § 493.1445(e) relating to the responsibilities of a laboratory director; and (2) whether the ALJ erred in sustaining the pre-hearing suspension of Petitioner's CLIA certificate as well as other sanctions.

Analysis

Petitioner makes two main arguments. First, Petitioner argues that substantial evidence in the record does not support the conclusion that Petitioner failed to ensure quality laboratory services because what CMS termed Petitioner's "allegation of compliance" was also confirmation that it had furnished *evidence* of compliance. Request for Review

⁴ Consolidation Order, dated January 21, 2016, Civil Remedies Division Docket Nos. C-15-2773 and C-16-200.

⁵ See CMS's Proposed Exhibit and Witness list.

(RR) at 5. Second, Petitioner argues that the ALJ erred when he upheld CMS’s principal sanction of suspension of Petitioner’s CLIA certificate⁶ and cancellation of its approval to receive Medicare payments on the grounds that Petitioner’s refusal to permit inspection of the laboratory was a reasonable basis for CMS to impose immediate suspension. *See id.* at 5-6. The ALJ Decision is supported by substantial evidence in the record and is free from legal error. Below we explain our reasoning.

1. *The ALJ decision is supported by substantial evidence in the record.*

As discussed above, the Board’s standard of review for a disputed issue of fact is whether the ALJ Decision is supported by substantial evidence in the administrative record as a whole.⁷ *See Guidelines*. Before the ALJ, the standard of proof concerning a CMS determination that a laboratory is not in compliance with CLIA conditions is preponderance of the evidence. CMS had the burden of coming forward with sufficient evidence to establish a prima facie case that the laboratory is not complying with one or more CLIA conditions. The laboratory then had the burden of showing by a preponderance of the evidence that it was in compliance with CLIA conditions. *Immuno Biogene, Inc.*, DAB No. 1946, at 2 (2004), and cases cited therein.

The ALJ found that CMS made a prima facie case for Petitioner’s CLIA non-compliance. ALJ Decision at 14. He further found that Petitioner’s “arguments that it made a good faith effort or a credible, but unverified allegation of compliance” failed to rebut CMS’s case. *Id.* In reaching that decision, the ALJ reasoned:

I find Petitioner’s arguments that it is compliant with CLIA because it 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. § [493.]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.

Id. Petitioner offers no evidence to rebut the evidence of its deficiencies but relies instead on the assertion that the ALJ mischaracterized the evidence he received. Petitioner’s argument is baseless. We will not catalog here each specific exhibit in the

⁶ Petitioner uses the word “license” but it is clear from the totality of Petitioner’s submissions that it refers here to its CLIA certificate. *See* RR at 5.

⁷ Substantial evidence means “such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Richardson v. Perales*, 402 U.S. 389, 401 (1971) (quoting *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938)).

administrative record which supports the ALJ's findings and conclusions. We have reviewed all of the evidence in the record, and the examples which we highlight below are sufficient to explain why we conclude that substantial evidence in the record supports the ALJ's decision.⁸

First, the ALJ correctly upheld CMS's determination that Petitioner was not in compliance with § 493.1445(e)(1) (Tag D6082). CMS presented evidence that Petitioner failed to ensure that its testing systems provided quality laboratory services for each test performed in the laboratory. ALJ Decision at 11. CMS's evidence included 1) that the director could not locate the operator's manual for several instruments; 2) that laboratory records lacked entries for initial equipment validation; and 3) that calibration worksheets lacked essential information. *Id.* In addition, the ALJ found that the evidence showed that the laboratory director could not demonstrate validation or proficient use of certain key laboratory equipment. *Id.* at 12.

Petitioner argued that staffing shortages and miscommunication about the placement of manuals impeded Petitioner's ability to produce records responsive to the surveyor's requests. ALJ Decision at 11. Petitioner contended that equipment had been validated prior to testing; however, Petitioner failed to furnish validation dates. *Id.* Petitioner also suggested that pipette calibration worksheets from a predecessor laboratory were responsive to validation requirements for the instant laboratory. *Id.* The ALJ considered Petitioner's lack of documentation and inability to produce the documentation it had on file to be the result of the disorganized state of the facility, which the surveyors had observed and documented. *See id.* at 12. Moreover, the ALJ discounted the fact that Petitioner was able to produce some missing equipment manuals by the second day of the initial survey visit because the information in those manuals lacked critical data such as validation dates for calibration of certain equipment. *Id.* at 13 n.5. CMS had rejected this submission in part because it contained records pertaining to another laboratory from

⁸ Our review of Petitioner's written arguments reveals that "good faith effort" is a characterization Petitioner used several times in its various briefs. For example, in its Opposition to CMS's Motion for Summary Judgment and Prehearing Brief in Docket. No. C-16-200, Petitioner states:

[]Petitioner has made *good faith efforts* to comply with CLIA regulations for the past two years, during which it made efforts to change its practices, as evidenced by its letters to CMS explaining new plans of correction and responses to alleged condition-level deficiencies.

Petitioner's Motion in Opposition and Prehearing Brief (Dkt. No. C-16-200) at 9 (*italics added*). In addition, in its Post Hearing Brief, Petitioner states:

Considering Petitioner's continued *good-faith efforts* to comply with CMS's mandates and [the director's] attempts to alert CMS of her emergency, there is no benefit gained by revoking Petitioner's CLIA certificate, without giving Petitioner the opportunity to prove it is in compliance with CLIA regulations and requirements.

Petitioner's Post-Hearing Brief at 7-8 (*italics added*). Petitioner nowhere explains, however, on what authority it bases its repeated reliance on good-faith efforts that fall short of complying with applicable requirements.

2001 and 2002, which CMS found irrelevant because they did not address whether Petitioner was then enrolled in proficiency testing for Chlamydia. CMS Ex. 17, at 12-16; CMS Ex. 19, at 3-4; CMS Ex. 37, at 8-9, ¶ 29.

Next, the ALJ upheld CMS's determination that Petitioner was not in compliance with § 493.1445(e)(3)(ii) (Tag D6086) because the laboratory failed to ensure that it had procedures for verifying, and actually did verify, its testing systems. *Id.* at 14. CMS's evidence included that Petitioner failed to show that it had verification procedures and validation for certain tests it performed.⁹ Petitioner manufactured many of the test kits it used; however, the surveyors noted that Petitioner failed to maintain procedures that instruct technicians on how to verify each test. *Id.* at 15. Moreover, when Petitioner was asked to furnish the surveyors with a validation log for tests using in-house procedures, Petitioner claimed that the surveyors had reviewed "the wrong sheet" without ever correcting the error by making the appropriate records available for inspection. *Id.* Petitioner also used test kits manufactured by other laboratories, which came with their own testing standards. *Id.* However, in the Plan of Correction that Petitioner submitted to CMS, Petitioner stated "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 [Petitioner's laboratory], i.e. ASO and Chlamydia pneumonia." ALJ Decision at 15 (citing CMS Ex. 1, at 18). The ALJ reasoned that this statement did not demonstrate compliance because the goal of the compliance standard is to "ensure that the laboratory verify the tests in its own environment to make sure that it could accurately and precisely perform the tests on human samples." *Id.*

The ALJ also correctly upheld CMS's determination that Petitioner was not in compliance with § 493.1445(e)(4) (Tag D6088) because the laboratory failed to ensure that it was enrolled in proficiency testing. ALJ Decision at 16. Petitioner admitted this failure, at least as to Chlamydia testing, in a pre-hearing brief.¹⁰ The ALJ rejected Petitioner's argument that it had "made a good faith effort to demonstrate substantial compliance" with the requirement. The ALJ gave no weight to certificates from trade associations which Petitioner submitted, and made no finding on the validity of the certificates, because Petitioner admitted it had not established any proficiency testing program for at least one test the laboratory performed (Chlamydia). *Id.* The ALJ correctly ruled that failing to demonstrate that it participated in an approved proficiency testing program for *any* test the laboratory performed constitutes non-compliance with

⁹ Some of the tests performed at the laboratory included Rheumatoid Factor, Antistreptolysin O (ASO) titer, Mycoplasma Antibody titer, and Chlamydia antibodies tests. ALJ Decision at 15.

¹⁰ "[The director] explained in Petitioner's plan of correction that '[t]he laboratory was not enrolled in PT [proficiency testing] for Chlamydia antibodies because inquiry from several PT organizations stated that they do not offer proficiency testing for *Chlamydia pneumonia*.[']". Petitioner's Memorandum in Opposition to CMS's Motion to Dismiss or For Summary Judgment and Pre-Hearing Brief, Docket No. C-15-2773, at 16.

the standard. *Id.* at 17 (citing *White Lake Family Med., P.C.*, DAB No. 1951, at 2 (2004); § 493.803(a)).

On review, the Board does not re-weigh the evidence or overturn an ALJ's "choice between two fairly conflicting views" of the evidence; instead, the Board determines whether the contested finding could have been made by a reasonable fact-finder "tak[ing] into account whatever in the record fairly detracts from [the] weight" of the evidence that the ALJ relied upon. *BGI Ret., LLC, d/b/a Crossbreese Care Ctr.*, DAB No. 2620, at 6 (2015) and the cases cited therein.

We conclude that the ALJ's findings of fact took into account Petitioner's evidence but that Petitioner's evidence did not significantly detract from the weight of the evidence supporting CMS's determination. Before the Board, Petitioner cites little evidence in the record, and makes no new legal argument.¹¹ Rather, in its Request for Review, Petitioner argues:

The ALJ's decision that Petitioner failed to ensure quality laboratory services is not supported by substantial evidence because the ALJ mischaracterized Petitioner's "credible allegation of compliance" as only a "good faith effort."

RR at 4 (citing ALJ Decision at 10-14). As we noted above, Petitioner itself, not the ALJ, characterized Petitioner's attempts at compliance as a "good faith effort." The ALJ rejected the Petitioner's attempt to equate a "good faith effort" with a credible allegation of compliance, reasoning that "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." ALJ Decision at 10.

On appeal to the Board, Petitioner's argument rests on the proposition that the information it submitted, which CMS deemed an allegation of compliance, was in itself sufficient to prove compliance. The record reflects that K.W. did reach the conclusion that the totality of Petitioner's submissions amounted to a minimally credible allegation of compliance. CMS Ex. 37, at 9 ¶¶ 30-32. However, Petitioner misunderstands the meaning of this finding. In its Request for Review, Petitioner argues that when CMS deemed Petitioner's submission a credible allegation of compliance, it "confirm[ed] that the information provided by Petitioner *provided evidence of compliance.*" RR at 5 (italics added). However, as the ALJ found, no evidence supports the conclusion that K.W.'s statement was a determination made by the surveying agency, *confirming* that the information provided by Petitioner provided *evidence of compliance.*" See *id.* at 5 (italics added). As the ALJ correctly points out:

¹¹ We also note that Petitioner filed no memorandum of law with its Request for Review, and Petitioner does not support its argument with any statutory or regulatory authority or any citation to a court or Board decision.

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, [CMS] may lift alternative sanctions – with rules related to principal sanctions. [. . .] [T]he state survey agency determined that it needed to conduct a revisit, which never occurred, so the credible allegation of compliance was never verified.

ALJ Decision at 19. Accordingly, the ALJ was correct to conclude that Petitioner’s allegation of compliance was, until confirmed via survey revisit, merely a preliminary step on the road toward demonstrating compliance and thus justifying relief from alternative sanctions. We discuss later in this decision the ramifications for Petitioner that its credible allegation of compliance was never verified by a revisit by the state survey agency.

The documents Petitioner submitted with its first request for ALJ hearing likewise fail to show compliance. The ALJ found that those documents were irrelevant because Petitioner had conceded that it was not enrolled in proficiency testing for (at least) one type of test (Chlamydia). *See* ALJ Decision at 16 (citing CMS Ex. 1, at 19). Further, as the ALJ points out, Petitioner cites these documents in its Prehearing Brief merely as proof that it had made a “good faith effort” toward a “substantial compliance” standard, and not as demonstrating compliance, as is required. *Id.* (citing Petitioner’s Prehearing Brief, Dkt. No. C-15-2773, at 15). The ALJ correctly reasoned that a laboratory’s failure to be tested for any examination and procedure for which it had received a CLIA certificate constituted failure to meet the applicable standard. *Id.* at 16-17 (citing 42 U.S.C. § 263a(f)(3)(A); *White Lake Family Medicine*, DAB No. 1951 (2004); and 42 C.F.R. 493.803(a)). The ALJ found that substantial evidence in the record established that Petitioner failed to meet three enumerated standards, and, as such, had failed to satisfy the Laboratory Director condition for certification. Applying Board precedent to these facts, the ALJ further reasoned that the 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. ALJ Decision at 10 (citing *Edison Med. Labs., Inc.*, DAB No. 1713, at 1-2); *see also id.* at 17 (citing *White Lake Family Med.* at 2). We conclude, therefore, that Petitioner’s contention that the record lacks evidence to support the ALJ’s decision is a specious one and we find no basis in it to disturb the ALJ’s decision.

2. *The ALJ did not err when he upheld CMS’s determination to impose sanctions.*

Petitioner contends that the ALJ erred when he upheld CMS’s decision to impose the principal sanctions of suspension and cancellation of Petitioner’s approval to receive Medicare payments for failure to comply with the Laboratory Director condition. RR at 5-6. In addition, Petitioner argues that the ALJ erred when he upheld CMS’s imposition

of immediate suspension for refusing a request to inspect the laboratory. *Id.* at 6. We address each assignment of error in turn.

Petitioner's sole argument supporting its first assignment of error is, in so many words, that Petitioner had made a credible allegation of compliance with the Laboratory Director condition, and therefore the resulting principal sanctions were baseless. *See id.* at 6. As discussed above, substantial evidence in the record supports the ALJ's conclusion that Petitioner had violated the Laboratory Director condition and Petitioner failed to rebut the evidence showing that it was non-compliant with three standards. We will not reiterate here our earlier discussion explaining that Petitioner's credible allegation of compliance was a preliminary step which, under the regulations, required a state survey agency revisit to confirm and verify the alleged compliance. *See* 42 C.F.R. § 493.1810(e). Petitioner's allegations of compliance were never confirmed; as such, they remained mere allegations. Petitioner points to no authority to support its argument that mere allegations, without evidence verified during a revisit, rebut CMS's bases established in the administrative record for the imposition of principal sanctions. Nor does Petitioner offer any authority to support its position that the ALJ erred in finding CMS had sufficient basis to suspend Petitioner's CLIA certificate for condition level deficiencies which do not rise to the level of immediate jeopardy, as provided for in § 493.1814(a)(2) of the regulations. Therefore, we conclude the ALJ did not err when he upheld CMS's imposition of principal sanctions for condition level non-compliance in this case.

Petitioner's allegations of compliance were never subject to confirmation for one reason: Petitioner failed to permit CMS to re-inspect its laboratory facility. The regulations provide that a laboratory issued a certificate must permit CMS or a CMS agent to conduct an inspection to assess the laboratory's compliance with CLIA requirements, and CMS or a CMS agent may re-inspect a laboratory at any time to evaluate the laboratory's ability to provide accurate and reliable test results. *See* § 493.1771; 493.1773(d), (f). CMS retains broad discretion under CLIA to select a course of action to ensure that laboratories remain in or promptly return to compliance with CLIA requirements. *Edison Med. Labs.* at 2 (citing 42 C.F.R. § 493.1800(a)(2)(iii); 57 Fed. Reg. at 7224). Originally, this included unannounced inspections. 63 Fed. Reg. 26,725 (May 14, 1998). In response to public comment, CMS instituted a general policy of announced inspections and reinspections, except for in certain cases, while maintaining that the Public Health Service Act provides for unannounced inspections. *See id.* CMS agreed with commenters that unannounced inspections would be a waste of inspectors time if, for example, at the time of the inspection, the laboratory was closed or the director happened to be unavailable in the absence of notice. *Id.* The Public Health Service Act subjects a laboratory to possible CLIA certificate suspension, even prior to a pending ALJ hearing, and to revocation for *refusal* of CMS's reasonable request for permission to inspect the laboratory. *See* § 353(i)(1)(E) of the Public Health Service Act; 42 C.F.R. §§ 493.1840(a), (a)(5), and (d)(2)(iii).

Petitioner argues that Petitioner 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.” RR at 6. First, the ALJ concluded that the request to inspect the facility was reasonable. ALJ Decision at 21. In reaching this conclusion, the ALJ reasoned:

CMS needed to verify Petitioner’s credible allegation of compliance, which seemed incredibly difficult to do. CMS scheduled and rescheduled its visits to accommodate Petitioner[.] . . . [R]ather 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. [Citation omitted.] 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.

ALJ Decision at 21-22 (citing CMS Exs. 20, at 1; 40, at 2). We agree that the inspection was reasonable. The regulations provide for laboratories to begin operating with CLIA registration, but require they submit to inspection before the certificate expires – that is, within two years of registration. *See* § 353(g)(1) of the Public Health Act; 42 C.F.R. § 493.45(c)(2), (3); CMS Ex. 38, at 3 ¶ 9. The state surveyor, G.M., testified that the state places newly certified laboratories on the schedule for an initial survey approximately three months after the laboratory begins operating. *Id.* In this case, Petitioner received CLIA certification September 9, 2013, and it appeared on G.M.’s schedule for survey in December 2013. *Id.* at 4 ¶12. It took Petitioner approximately eight months to permit G.M. to conduct the initial survey visit. *Id.* at ¶11. Once G.M. conducted the initial survey visit, more than a year elapsed before Petitioner finally submitted what CMS deemed a credible allegation of compliance, precipitating the need for a survey revisit to verify that all corrections had been made. *See* CMS Ex. 37, at 9 ¶32; CMS Ex. 20 at 2 (CMS notice to Petitioner, dated August 4, 2015, of impending survey revisit). Thus, the revisit request was reasonable because the regulations required Petitioner to permit verification of its allegations of compliance or risk expiration of its CLIA certification and also because of the context of delays and resistance. Whether or not Petitioner understood this, it was in Petitioner’s interest to permit the required revisit as scheduled. We agree with the ALJ that nothing was unreasonable about the attempted revisit or its scheduling. We next address the exigencies that Petitioner alleges prevented the laboratory director from attending at the appointed time or providing a suitable surrogate.

Petitioner argues that the laboratory director's "medical condition," overnight emergency department visit, and ensuing absence for the revisit at the previously agreed upon, scheduled time and date, was "no fault of her own." RR at 6-7. Petitioner stresses the director's "good-faith effort" to notify CMS of her emergency and attributes the failure to contact CMS to her attorney's unavailability due to a court appearance. *Id.* This, Petitioner contends, does not amount to refusal. *Id.* at 7-8.

The ALJ reviewed the unique facts and circumstances surrounding this Petitioner's CLIA inspection process. ALJ Decision at 22. As the ALJ observed, refusal is not defined in the statute, regulations, or legislative or regulatory history for the respective provisions. ALJ Decision at 23. The ALJ found Petitioner's and CMS's arguments based on the Board's decision in *US Bio-Chem Medical Laboratories, Inc.*, DAB No. 1731 (2000) unhelpful because the facts were readily distinguishable from the facts here.¹² ALJ Decision at 21. The ALJ also noted that no clear definition of refusal resulted from the *US Bio-Chem* decision because the refusal – the affirmative act by a laboratory official to deny the surveyor's request for and prevent the surveyor's access to information – was clear on its face. CMS argued, and the ALJ agreed, that such a definition of refusal is too narrow, and in view of the broad statutory authority to inspect laboratories granted the Secretary under CLIA, we also agree.

Absent a definition of refusal in CLIA or the implementing regulations, the ALJ looked to provisions in the Federal Food, Drug, and Cosmetic Act for guidance. ALJ Decision at 23. In doing so, the ALJ considered the long history of inspections conducted by another HHS component, the Food and Drug Administration, which led to federal court decisions. *Id.* at n.7. However, we need not adopt this facet of the ALJ's analysis to agree, generally, with the basic outline of the ALJ's reasoning here¹³.

The ALJ concluded that Petitioner refused a reasonable request for inspection because, the unique history of recalcitrance exhibited by the laboratory director here was inconsistent with a laboratory in full compliance, which, he reasoned, "would be eager to schedule a visit as soon as possible in order to maintain its status as a CLIA laboratory." ALJ Decision at 21-22. We agree that Petitioner's refusal is evidenced by the laboratory director's conduct throughout the pendency of the survey. As CMS noted, Petitioner "failed to respond timely to 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." ALJ Decision at 22 (citation omitted). That the laboratory director "failed to

¹² In *US Bio-Chem*, a laboratory official interceded to prevent laboratory staff from complying with a surveyor's request to review a log book.

¹³ We decline to adopt the ALJ's analysis based on the Federal Food, Drug and Cosmetics Act for several reasons, including the fact that (as the ALJ points out) refusal of an FDA inspection is a criminal offense. ALJ Decision at 23. No criminal penalties result from refusal of a CLIA inspection. We view the comparison with a statute which contemplates criminal penalties not useful in the context of CLIA appeals.

appear for the scheduled and announced revisit and failed to inform surveyors beforehand that [the director] would not be present” was only the latest in a series of acts we can only view as defiant. *See id.* Indeed, the laboratory director’s refusal to appear for the revisit knowingly wasted “an extraordinary amount of the surveyors’ time.” *Id.* at 24 (citing CMS Ex. 37, at 11). As discussed above, one of the reasons CMS agreed to forgo unannounced inspections was to avoid such waste of time. 63 Fed. Reg. 26,725. Therefore, we conclude that, within the context of the events transpiring between December 2013 and September 2015 in this case, Petitioner’s conduct was the kind of refusal to permit inspection of the laboratory contemplated under the regulations.

Petitioner did not challenge the ALJ’s decision upholding CMS’s imposition of principal sanctions on any other grounds. Having concluded that the ALJ did not err when he found reasonable the request for reinspection and found that Petitioner refused the request, we sustain the ALJ’s decision.

Conclusion

For the foregoing reasons, we sustain the ALJ’s decision upholding the cancellation of Petitioner’s approval to receive Medicare reimbursements and the suspension and revocation of Petitioner’s CLIA certificate.

_____/s/
Leslie A. Sussan

_____/s/
Constance B. Tobias

_____/s/
Christopher S. Randolph
Presiding Board Member