Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Liberty Laboratory, Inc.
Docket No. A-14-23
Decision No. 2562
March 24, 2014

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Liberty Laboratory, Inc. (Liberty) appealed the November 14, 2013 decision of an Administrative Law Judge (ALJ) granting summary judgment for the Center for Medicare & Medicaid Services (CMS) and upholding CMS's revocation of Liberty's certificate to operate as a clinical laboratory. *Liberty Laboratory, Inc.*, DAB CR2995 (November 14, 2013) (ALJ Decision). For the reasons explained below, we uphold the ALJ Decision.

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. One condition is that a "laboratory performing non-waived testing must successfully participate in a proficiency testing program approved by CMS…for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA." 42 C.F.R. § 493.803(a). Generally, if a laboratory fails to successfully participate in proficiency testing (PT), CMS imposes one or more sanctions, which may include revocation of the laboratory's CLIA certificate. *Id*. §§ 493.803(b), 493.1800, 493.1804(b). The regulations define the term "unsuccessful participation in proficiency testing" to include "[u]nsatisfactory performance for the same analyte in two consecutive or two out of three testing events." *Id*. § 493.2. The term "unsatisfactory proficiency testing performance" is defined as "failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event." *Id*.

The following facts are undisputed. Liberty had a CLIA certificate to perform non-waived, moderate complexity testing for the subspecialty of routine chemistry (among others). In an August 2012 survey, the Indiana State Department of Health found that Liberty was not in compliance with three conditions of participation, including the condition of participation at section 493.803. The Statement of Deficiencies for the survey alleged that Liberty did not successfully participate in PT because it had scores below 80% for four analytes under routine chemistry (chloride, HDL cholesterol, sodium

and digoxin) for two consecutive or two out of three consecutive testing events. CMS notified Liberty by letter dated October 16, 2012 that it was imposing sanctions including revocation of Liberty's CLIA certificate effective November 5, 2012, unless a hearing was requested. Liberty requested a hearing before an ALJ. ALJ Decision at 1-2, 7.

After the ALJ issued a prehearing order, CMS filed a motion for summary judgment based on the alleged violation of section 493.803. CMS filed 20 exhibits in support of its motion, which the ALJ admitted without objection. Liberty submitted a "Pre-Hearing Brief," which the ALJ also treated as Liberty's response to CMS's motion, without any supporting exhibits.[1] ALJ Decision at 2. The ALJ determined that "there are no genuine disputes as to the material facts that establish a prima facie showing of noncompliance with" section 493.803 since Liberty did not dispute that it had a CLIA certificate to perform routine chemistry and that it failed to successfully participate in approved PT for routine chemistry. *Id*. at 8. The ALJ proceeded to analyze Liberty's "explanations for why the failures occurred," but concluded that "even if I accept [Liberty's] allegations of fact as true, as a matter of law [Liberty] can establish no defense to excuse its noncompliance with the condition-level requirement established by 42 C.F.R. § 493.803." *Id*. at 7, 9. Accordingly, the ALJ granted CMS's motion and revoked Liberty's CLIA certificate effective on the date of his decision.[2] *Id*. at 10.

Whether summary judgment is appropriate is a legal issue that we address de novo. Summary judgment is appropriate if there are no genuine disputes of fact material to the result. In reviewing whether there is a genuine dispute of material fact, we view proffered evidence in the light most favorable to the non-moving party. *See Livingston*

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[1] Liberty stated in its Pre-Hearing Brief as well as in its Request for Appellate Review (RR) that "[p]art of the exhibits submitted in this case concerned police reports in which former employees removed key information before leaving employment at Liberty Laboratory." Pre-Hearing Br. dated 7/19/13,at 1; RR at 1 (emphasis added). Prior to submitting its Pre-Hearing Brief, Liberty submitted a List of Proposed Exhibits which described Exhibit 5 as "Police Reports filed with the Tell City Police Department." However, Liberty did not file any proposed exhibits with its list and stated in its letter transmitting the list only that it had sent a copy of the proposed exhibits to the respondent (CMS). Letter dated 5/20/13. This was consistent with the ALJ's Acknowledgement and Prehearing Order, which stated in relevant part:

> The parties will not file copies of exhibits or other evidentiary materials with the CRD [the Civil Remedies Division, which provides support to the ALJs] at the time of their initial exchanges….When the parties serve their initial exchange upon the opposing party, they will file a record copy and two additional copies of their witness list and exhibit list only with the CRD. **The parties will file a record copy and two additional copies of any documentary evidence to be considered in deciding this case with their PREHEARING BRIEFS.**

Acknowledgement and Prehearing Order dated 12/26/12, at 3 (emphasis in original). Even if the exhibit in question had been submitted, it would not advance Liberty's case. As indicated in our discussion below, Liberty's assertion that its former employees removed certain information (which the ALJ accepted as true for purposes of summary judgment) does not raise a dispute of material fact.

[2] The regulations provide that "CMS does not revoke any type of CLIA certificate until after an ALJ hearing that upholds revocation." 42 C.F.R. § 1840(e)(1).

Care Ctr., DAB No. 1871 at 5 (2003), *aff'd, Livingston Care Ctr. v. U.S. Dep't of Health & Human Servs.*, 388 F.3d, 168, 172-73 (6th Cir. 2004); *Celotex Corp. v Catrett*, 477 U.S. 317, 322-25 (1986). Our 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 Laboratory Improvement Amendments and Related Statutes*, available at http://www.hhs.gov/dab/divisions/appellate/guidelines/clia.html.

On appeal, Liberty merely reiterates some of its arguments below, which the ALJ found lacked merit. Liberty alleges that the "lead inspector on the day of inspection" was a man against whom the laboratory director had previously filed sexual harassment charges and who the state agency had agreed would not have further contact with the laboratory director. RR at 1. In addition, Liberty alleges that the "other 2 inspectors were still in training." *Id*. The ALJ accepted these allegations as true but noted that Liberty does not assert that "the survey team composition had any impact upon the unsatisfactory PT scores[.]" ALJ Decision at 9.[3] Liberty does not assert on appeal that there was any such impact, nor could it reasonably do so since, as the ALJ also noted, the unsatisfactory PT scores were received "months prior to the survey." *Id*. As the Board has previously stated, "where objective evidence establishes the existence of a deficiency, it would make little difference whether or not a particular surveyor was biased against a particular facility." *Canal Medical Lab.*, DAB No. 2041, at 5-6 (2006); *see also Edison Medical Labs., Inc.*, DAB No. 1713, at 16, 19-20 (1999) (allegations of surveyor bias and procedural flaws in conduct of survey irrelevant where evidence demonstrated laboratory's failure to meet required conditions), *aff'd, Edison Medical Lab., Inc. v. Health Care Fin. Admin.*, 250 F.3d 735 (3rd Cir. 2001) (unpublished table decision). Accordingly, we agree with the ALJ that Liberty's allegations regarding the composition of the survey team do not raise a dispute of material fact precluding summary judgment in CMS's favor.

Liberty also alleges that police reports showed that former employees of Liberty "removed key information before leaving employment at" Liberty. RR at 1. The ALJ accepted this allegation as true but noted that Liberty does not assert that "there is any connection between the materials allegedly stolen and the PT failures and noncompliance

[3] It appears that the ALJ was addressing both allegations although his decision mentions only the allegation regarding the lead inspector.

with 42 C.F.R. § 493.803." ALJ Decision at 9. Liberty does not assert on appeal that there was any such connection.[4] Accordingly, we agree with the ALJ that Liberty's allegation that documents were removed without its permission does not raise a dispute of material fact precluding summary judgment in CMS's favor.

Liberty alleges further that due to "extreme" events in the personal life of the laboratory director, she relied on a laboratory employee "to help with the review of all aspects of the laboratory." RR at 2. According to Liberty, it later found that this employee "was working for a competitor" and that she was "named in the police reports as the person overhea[r]d talking about removing key corrective actions and other important CLIA documents from the laboratory." *Id*. The ALJ accepted these allegations as true, but noted that Liberty "cites no legal authority for the proposition that [its] condition-level noncompliance with 42 C.F.R. § 493.803 may be or should be excused simply because [the laboratory director] was not fully executing her duties to oversee laboratory operations[.]" ALJ Decision at 10.

The CLIA regulations provide that "the laboratory director is responsible for the overall operation and administration of the laboratory … and for assuring compliance with the applicable regulations." 42 C.F.R. § 493.1407. The regulations further provide that "[i]f the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed." *Id*. § 493.1407(b). Thus, as a matter of law, Liberty cannot disavow responsibility for its unsuccessful participation in PT by claiming that its laboratory director delegated her responsibilities to someone else. We therefore agree with the ALJ that Liberty's allegations regarding the circumstances under which the laboratory director delegated some of her responsibilities and the untrustworthiness of the employee to whom she delegated those responsibilities do not raise a dispute of material fact.

Finally, Liberty asserts that the state survey agency did not follow "[n]ormal procedures" to "immediately notify the laboratory" that the laboratory does not have a passing score on two PT events in a row and provide "a short time frame in order to get the laboratory back in compliance." RR at 2. The ALJ stated that Liberty "describes the procedure at 42 C.F.R. § 493.803(c)." ALJ Decision at 10. That provision, quoted on page 8 of the ALJ Decision, authorizes CMS, under certain circumstances where there is "initial unsuccessful performance" of PT, to direct a laboratory to undertake training of its

[4] We note that Liberty stated in a submission accompanying its corrective action plan that "2 employees that left abruptly removed documentation that the inspectors needed," which it identified as quality assurance records and calibration records. CMS Ex. 16, at 33. However, that submission did not claim that such records could have established that Liberty successfully participated in PT.

personnel or to obtain technical assistance, or both, instead of imposing sanctions including revocation.[5] The ALJ concluded that the regulation by its own terms does not apply where there is a finding of immediate jeopardy or the laboratory has a poor compliance history and was therefore inapplicable to Liberty, which had both a finding of immediate jeopardy and a history of noncompliance. ALJ Decision at 8, 10. The ALJ further concluded that in any event he would have no authority to review a decision by CMS not to permit training or technical assistance instead of imposing sanctions. *Id*. Liberty does not point to any error in these conclusions. Accordingly, we agree with the ALJ that "this issue must be resolved against [Liberty] as a matter of law[.]" *Id*. at 10.

Conclusion

For the foregoing reasons, we uphold the ALJ's decision granting summary judgment to CMS and revoking Liberty's CLIA certificate effective on the date of his decision.

/s/
Sheila Ann Hegy

/s/
Constance B. Tobias

/s/
Leslie A. Sussan
Presiding Board Member

[5] By "initial unsuccessful performance," section 493.803(c) appears to mean the first instance of "unsuccessful participation in proficiency testing" as defined in section 493.2, not the first instance of "unsatisfactory proficiency testing performance" as defined in section 493.2, since only the former would be a basis for imposing sanctions if CMS does not exercise its authority under section 493.803(c) or section 493.803(c) does not apply.