Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	)	
	)	
Associated Internists, P.C.,	)	DATE: January 27, 2010
	)	
	)	Civil Remedies CR2005
Petitioner,	)	App. Div. Docket No. A-10-10
	)	
	)	Decision No. 2298
- v. -	)	
	)	
Centers for Medicare & Medicaid Services.	)	
	)	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Associated Internists, P.C., (Associated), a clinical laboratory, appeals the September 16, 2009, decision of Administrative Law Judge Steven T. Kessel. Associated Internists, P.C., DAB CR2005 (2009) (ALJ Decision). The ALJ dismissed Associated's hearing request challenging the Centers for Medicare & Medicaid Services' (CMS) suspension and revocation of its certificate under the Clinical Laboratories Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a et seq., and CMS's cancellation of its approval to receive Medicare payment. The ALJ dismissed the hearing request because he concluded that it failed to "state an issue that I may hear and decide." ALJ Decision at 4.

For the reasons set forth below, we uphold the ALJ Decision.

Standard of Review

The standard of review on factual issues is whether the ALJ decision is supported by substantial evidence in the whole record. The standard of review on issues of law is whether the

ALJ decision is erroneous. See Board Guidelines - Appellate Review of Decisions of Administrative Law Judges in Cases under CLIA and Related Statutes, http://www.hhs.gov/dab/guidelines/clia.html; U.S. Bio-Chem Medical Laboratories, Inc., DAB No. 1731 (2000).

Applicable law

Part 493 of 42 C.F.R. implements CLIA by, among other things, "set[ting] forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under [CLIA]." 42 C.F.R. § 493.1. Tests are categorized by complexity, and there are CLIA certification conditions (or requirements for "waived tests") specific to each category. See 42 C.F.R. §§ 493.5, 493.20, 493.25 and the subparts cited therein. Each certification condition represents a general requirement that must be met, and CLIA standards are the specific components of the conditions. 42 C.F.R. Part 493; see Edison Medical Laboratories, DAB No. 1713, at 2 (1999), aff'd, Edison Medical Lab. v. Thompson, 250 F.3d 735 (3rd Cir. 2001).

A laboratory's 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). Principal sanctions include suspension, limitation, or revocation of a laboratory's CLIA certificate (42 C.F.R. § 493.1806(b)), and, for laboratories participating in Medicare, cancellation of the laboratory's approval to receive Medicare payment for its services (42 C.F.R. § 493.1807(a)).

A laboratory may appeal CMS actions that constitute "initial determinations," as that term is defined in 42 C.F.R. § 493.1844(b). 42 C.F.R. § 493.1844. The ALJ hearing procedures and Board review provisions in 42 C.F.R. Part 498, subparts D and E, apply to such appeals. 42 C.F.R. § 493.1844(a). An ALJ may dismiss a hearing request if the laboratory does not have a right to a hearing. 42 C.F.R. § 498.70(b).

Background[1]

Associated is a clinical laboratory in Southfield, Michigan subject to the requirements of CLIA.

[1] The following background information is drawn from the ALJ Decision and the record. It is not intended to substitute for or modify any of the ALJ's findings.

On March 5, 2009, the Michigan Department of Community Health (MDCH) completed a survey of Associated to determine its compliance with CLIA standards and conditions. CMS Ex. 1.

On March 20, 2009, CMS sent Associated a Statement of Deficiencies (SOD) setting forth MDCH's noncompliance findings from the March survey. CMS Exs. 1, 2. It informed Associated that, based on the survey findings, CMS had concluded that Associated was out of compliance at the immediate jeopardy level with three CLIA conditions.[2] CMS stated that it therefore proposed to impose sanctions against Associated consisting of suspension and revocation of its CLIA certificate, cancellation of its approval to receive payments from Medicare for its services, and a directed plan of correction. CMS Ex. 2, at 2. As to the cited deficiency findings, CMS gave Associated ten days to file "written evidence or any other information against imposition of the sanctions," including a "written allegation of compliance" and supporting documentation (hereinafter referred to as a Plan of Correction (POC)). Id. CMS informed Associated that "[s]anctions can be lifted only when compliance with the referenced CLIA requirement is verified as achieved." Id. Finally, CMS informed Associated of its right to request an ALJ hearing challenging CMS's findings of noncompliance and the resulting sanction determination. CMS explained that --

> [t]he request for hearing must contain a statement as to the specific issues and findings of fact and conclusions of law in this determination with which the laboratory disagrees and the basis for the laboratory's contention that the specific issues and/or findings and conclusions are incorrect.

Id. at 4 (emphasis added).

On April 4, 2009, CMS received from Associated a POC. CMS Ex. 3, at 1. CMS reviewed the plan and determined that Associated had removed the immediate jeopardy. However, CMS also concluded

[2] The three CLIA condition-level deficiencies arose under 42 C.F.R. § 493.1230 (General Laboratory Systems), 42 C.F.R. § 493.1250 (Analytic Systems), and 42 C.F.R. § 493.1441 (Laboratory Director for laboratories performing high complexity testing). CMS Ex. 1; CMS Ex. 2, at 1. These three condition-level deficiency findings were based on the laboratory's alleged noncompliance with 22 specific CLIA standards as described in the SOD. CMS Ex. 1.

that the POC did not constitute a "credible allegation of compliance and acceptable evidence of correction of the deficiencies . . . ." Id. at 1-2. CMS wrote to Associated on April 15, 2009, advising Associated of these conclusions and that the sanctions proposed in the March 20 letter would take effect April 15, 2009. Id. at 1-4.[3]

On May 4, 2009, Associate filed a hearing request, stating that it was a "request for an appeal to remove the sanctions imposed upon [Associated] due to Allegation of Compliance Not Credible on the cited deficiencies during March 5, 2000 [sic] on site survey." CMS Ex. 5. The request described corrective actions Associated had taken and intended to take in response to the March survey findings.

The case was assigned to an ALJ. CMS then filed a motion to dismiss the hearing request, supported by five exhibits. CMS argued that Associated's hearing request did not "specify issues, and the findings of fact and conclusions of law" in the March survey with which Associated disagreed, as required by 42 C.F.R. § 498.40(b). CMS also argued that, to the extent Associated was seeking to appeal CMS's rejection of Associated's POC, Associated had no right under 42 C.F.R. § 493.1844 to appeal this rejection. CMS Motion To Dismiss at 5. Associated did not reply to CMS's motion.

The ALJ dismissed Associated's hearing request based on his determination that the hearing request did not comply with the specificity requirements of section 498.40(b) and did "not state an issue that I may hear and decide." ALJ Decision at 4.

Analysis

For the following reasons, we conclude the ALJ did not err in determining that Associated failed to identify an initial determination subject to appeal under 42 C.F.R. § 493.1844, the regulation governing appeals of CLIA sanctions, and that Associated's hearing request did not comply with the requirements of 42 C.F.R. § 498.40(b) for CLIA hearing requests.

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[3] Associated made a second submission to CMS dated April 23, 2009 regarding its post-survey remediation efforts. CMS Ex. 4. On April 30, 2009 CMS wrote to Associated and again explained why its allegations of compliance were not credible. Id. CMS reiterated that it was imposing the sanctions that were described in the March 20 letter.

As CMS stated in moving for dismissal before the ALJ, appeals in CLIA cases are authorized under 42 C.F.R. § 493.1844. Section 493.1844(b) provides that a laboratory may appeal CMS's "initial determinations" and lists four actions that constitute initial determinations. Section 493.1844(c) provides that "[a]ctions that are not listed in paragraph (b) of this section are not initial determinations and therefore are not subject to appeal under this section." (Emphasis added.) The four actions listed as initial determinations under section 493.1844(b) are:

> (1) The suspension, limitation, or revocation of the laboratory's CLIA certificate by CMS because of noncompliance with CLIA requirements.
>
> (2) The denial of a CLIA certificate.
>
> (3) The imposition of alternative sanctions under this subpart (but not the determination as to which alternative sanction or sanctions to impose).
>
> (4) The denial or cancellation of the laboratory's approval to receive Medicare payment for its services.

Associated did not challenge CMS's suspension and revocation of its CLIA certificate and cancellation of its approval to receive Medicare payment "because of noncompliance with CLIA requirements" identified in the March SOD as unauthorized or unsupported. Instead, as the ALJ correctly determined, "[w]hen read closely, the hearing request is not really a challenge to CMS's determinations [in the March survey] so much as it appears to be yet another attempt by [Associated] to assert that it has regained compliance with CLIA requirements."[4] Id.

[4] Associated's one-page request for review to the Board supports the ALJ's inference. The request for review fails to specify any finding of fact or conclusion of law by CMS about the March survey or by the ALJ in the ALJ Decision with which Associated disagrees. See 42 C.F.R. § 498.82. Instead, Associated acknowledges that it was found out of compliance with CLIA conditions in the March survey, describes steps it has taken and will take to "ensure that the laboratory practices and procedures are in compliance with Federal & State Rules." Request for Review. Associated attaches to the request for review a document that it characterizes as its "revised Plan of Correction" and states that it "would like to resubmit corrective measures." Id. Associated states in conclusion: "We hope and pray that after your review the revised plan of action [will] be accepted . . . ." Id.

We agree with the ALJ that Associated's hearing request reflects Associated's continuing misunderstanding about laboratories' appeal rights in CLIA cases and the bases for the sanctions here. These sanctions were imposed because of condition-level deficiencies identified in the March survey and not, as Associated appears to believe, because Associated failed to submit credible allegations of compliance after the survey. Indeed, the CLIA regulations do not require CMS to afford a laboratory the opportunity to correct condition-level deficiencies for which CMS has proposed principal sanctions, nor is there any provision in the regulations for an opportunity to challenge CMS's rejection of allegations of corrections. As CMS previously asserted in moving for dismissal of the hearing request, CMS's rejection of a laboratory's POC is not listed as an initial determination under section 493.1844(b), and the Board has specifically held that such a rejection is not an initial determination as defined by 42 C.F.R. § 493.1844(b) and not appealable. CMS Motion to Dismiss at 7-9, citing HRT Laboratory, Inc., DAB No. 2118 (2007). Associated offered no arguments as to why the holding and reasoning in HRT Laboratory are not applicable here.

Furthermore, as the ALJ found, Associated failed, despite ample opportunity, to submit a hearing request that complied with regulatory requirements. Section 498.40(b) sets forth specificity requirements for hearing requests in CLIA appeals, requiring that a hearing request must --

> (1) Identify the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and
>
> (2) Specify the basis for contending that the findings and conclusions are incorrect.

42 C.F.R. § 498.40(b). As the ALJ discussed, Associated's hearing request failed to adequately identify findings of fact or conclusions of law related to the March survey with which Associated disagreed and did not specify any bases for contending that CMS's findings and conclusions were incorrect. The ALJ found that the request referred to only two of the standard-level noncompliance findings in the SOD, without contesting them, and did not even mention the remaining deficiencies. ALJ Decision at 4. As to the two findings that Associated did discuss, the ALJ found that Associated essentially admitted that the findings were valid and "address[ed] post-survey remediation" and "not the question of compliance at the time of the survey." Id. Finally, the ALJ pointed out that, even if he disregarded the two standard-level

findings Associated did identify, the other findings remained unchallenged (and thus a basis for the imposition of the sanctions at issue). Id. In its request for review to the Board, Associated did not challenge any of the ALJ's findings or identify an error by the ALJ in applying the requirements of section 498.40(b) to Associated's hearing request.

For the preceding reasons, we conclude that the ALJ was authorized to dismiss Associated's hearing request under section 498.70(b) because Associated had no right to a hearing under section 493.1844 to challenge CMS's rejection of the POC that Associated submitted in response to the March survey and because the request failed to identify, as required by section 498.40(b), specific issues, findings, or conclusions with which Associated disagreed that were related to that survey.

Conclusion

We uphold the ALJ Decision.

/s/
Judith A. Ballard

/s/
Constance B. Tobias

/s/
Leslie A. Sussan
Presiding Board Member