Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Mohave Clinical Laboratory/Rustom Ali, Ph.D.,

Petitioner,

v.

Centers for Medicare & Medicaid Services,

Respondent.

Docket No. C-15-956

ALJ Ruling No. 2016-1

Date: October 14, 2015

DISMISSAL

Mohave Clinical Laboratory/Rustom Ali, Ph.D. (Petitioner), applied for a certificate under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. The Centers for Medicare & Medicaid Services (CMS) informed Petitioner that it is unable to process Petitioner's application due to unresolved issues related to a previous sanction action involving Sonali Diagnostic Laboratory (Sonali), another laboratory owned by Dr. Ali. Petitioner filed a motion for partial summary judgment and CMS filed a motion to dismiss the request for hearing.

Based on the pleadings before me, I conclude that CMS has not issued initial or reconsidered determinations denying Petitioner's CLIA application. Without a reconsidered determination, I have no jurisdiction to decide the merits of this case. Therefore, I grant CMS's motion to dismiss because Petitioner has no right to a hearing before an Administrative Law Judge (ALJ).

I. Background

Dr. Ali previously owned and operated at least two CLIA laboratories. One of those CLIA laboratories was Sonali.[1] In 2001 CMS issued an initial determination imposing the following sanctions on Sonali: a $30,000 civil money penalty (CMP); a directed plan of correction that required Sonali to cease testing on August 4, 2001; cancelation of approval to receive Medicare and Medicaid payments; and revocation of Sonali's CLIA certificate. On appeal, an ALJ upheld the sanctions CMS imposed, *Sonali Diagnostic Laboratory*, DAB CR1267 (2005), and the Departmental Appeals Board (DAB) affirmed the ALJ's decision. *Sonali Diagnostic Laboratory*, DAB No. 2008 (2006). An appellate court affirmed the DAB's decision, *Ali v. United States Department of Health and Human Services*, 240 Fed. Appx. 211 (2007), and Dr. Ali unsuccessfully sought United States Supreme Court review. *Ali v. Department of Health and Human Services*, 555 U.S. 924 (2008), *reh'g denied*, 555 U.S. 1128 (2009). Due to the sanctions imposed on Sonali, Dr. Ali was also prohibited from serving as the director of a CLIA certified laboratory. 42 U.S.C. § 263a(i)(3).

On April 17, 2013, a state agency working with CMS received Petitioner's application for CLIA certification. In an April 23, 2013 letter, CMS informed Dr. Ali that the CLIA application for Mojave Clinical Laboratory could not be processed due to "outstanding issues" related to the sanctions imposed on Sonali. CMS Exhibit (Ex.) 1 at 1. The CMS letter explained:

> To date, CMS has not received the signed attestation, or payment of the CMP. Nor have we received the laboratory's client list, which you were ordered to submit pursuant to a Directed Plan of Correction (POC) imposed on August 4, 2001. CMS cannot entertain - and will not process - any application for CLIA certification submitted by you or on your behalf as an owner, operator or director of a laboratory unless and until you:

[1] Dr. Ali was also the owner and operator of Scottsdale Medical Laboratory. In 2002, CMS issued an initial determination imposing the sanctions of revocation of Scottsdale Medical Laboratory's CLIA certificate and a civil money penalty. On appeal, an ALJ upheld the revocation of the CLIA certificate, but reversed the civil money penalty. *Rustom Ali, Ph.D., Owner and Operator of Scottsdale Medical Laboratory*, DAB CR1280 (2005). The Departmental Appeals Board affirmed the ALJ's decision to uphold revocation of the CLIA certificate. *Rustom Ali, Jahan Ferdous, and Scottsdale Medical Laboratory*, DAB No. 2016 (2006). An appellate court affirmed the Departmental Appeals Board's decision. *Ali v. United States Department of Health and Human Services*, 235 Fed. Appx. 676 (9th Cir. 2007).

> - Submit Sonali's Client List in accordance with the 2001 Directed POC;
> - Submit the signed attestation [provided in a January 2005 notice];
> - Pay in full the delinquent CMP, plus accrued interest.
>
> If and when you satisfy these requirements, CMS may consider a new application for CLIA certification of a laboratory at the above-referenced location. To be considered, any such application must nominate a director and technical supervisor who meet CLIA requirements.

CMS Ex. 1 at 2.

It appears that from September 2013 through May 16, 2014, Dr. Ali's counsel and CMS counsel attempted to resolve the issues raised in CMS' April 23, 2013 letter. Petitioner's Response at 8-9. The final communication from CMS on this issue appears to be a December 18, 2014 email in which CMS reiterated that Dr. Ali must comply with the terms stated in the April 23, 2013 letter. Petitioner's Response at 10.

On December 19, 2014, Petitioner requested a hearing before an ALJ. In a January 15, 2015 letter, the Civil Remedies Division informed Petitioner that it must submit a copy of CMS's reconsidered determination. Petitioner responded that CMS's determinations in this case were the April 23, 2013 letter, a May 16, 2014 email from CMS counsel, and a December 18, 2014 email from CMS. Petitioner's Response at 1, 3. After being assigned to hear and decide this case, I issued an acknowledgement and pre-hearing order on January 26, 2015.

On February 21, 2015, Petitioner filed a motion for summary judgment (P. Br.) in which it argued that CMS denied its CLIA application and, in so doing, failed to provide notice of Petitioner's right to an ALJ hearing. P. Br. at 1-2. Petitioner urged me to reverse CMS based on depravations of his due process. P. Br. at 3. On February 21, 2015, Petitioner filed an attachment to his motion for summary judgment, which largely consisted of arguments as to why the decisions involving Sonali were defective.

On March 20, 2015, CMS filed a brief that both moved for dismissal of the hearing request and opposed Petitioner's motion for summary judgment. In its motion to dismiss CMS asserted that it had not taken any action related to Petitioner that is an initial determination under the regulations. CMS Brief at 4. Further, CMS argued that even if CMS's April 23, 2013 letter could be construed as an initial determination to deny Petitioner's application, Petitioner still does not have a right to an ALJ hearing because

there was no reconsideration request. CMS Brief at 4-5. CMS submitted a copy of the April 23, 2013 CMS letter as CMS Exhibit 1.

Petitioner filed a rebuttal and asserted that CMS's refusal to process its CLIA certification application was effectively a denial of the application because CMS will not approve the application until the conditions stated in the April 23, 2013 letter are met. Petitioner's Rebuttal at 1, 3-4. Further, Petitioner asserts that the emails from 2013 and 2014 are sufficient to prove that CMS issued a reconsidered determination. Petitioner's Rebuttal at 2. Petitioner also submitted a correction in which Petitioner indicated that its motion for summary judgment was in fact meant as a motion for partial summary judgment.

On April 15, 2015, I stayed the prehearing exchange schedule in order to consider the dispositive motions submitted by the parties.

II. Discussion

Laboratories and prospective laboratories dissatisfied with an "initial determination" related to CLIA are entitled to ALJ review of that initial determination under the procedures in 42 C.F.R. Part 498. 42 C.F.R. § 493.1844(a)(1)-(2). The following actions are "initial determinations" and, therefore, subject to appeal:

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.

42 C.F.R. § 493.1844(b). Actions not listed above are not "initial determinations" and, therefore, are not subject to appeal under the CLIA appeal regulations. 42 C.F.R. § 493.1844(c).

If CMS denies a CLIA certificate, then the prospective laboratory must request CMS to reconsider the denial before seeking ALJ review. 42 C.F.R. § 493.1844(e)(1). If the prospective laboratory is dissatisfied with the reconsidered determination, then the prospective laboratory is entitled to an ALJ hearing. 42 C.F.R. § 493.1844(e)(3).

In the present matter, Petitioner asserts that it has received three denials from CMS concerning his application for a CLIA certificate. Petitioner's Response at 1, 3. In order for a prospective laboratory to have a right to ALJ review, the prospective laboratory

must be able to show that it has received an initial determination and a reconsidered determination. Here, Petitioner has received neither.

CMS did not deny Petitioner's CLIA application, but rather informed Petitioner that CMS could not process the application due to various outstanding issues. CMS Ex. 1 at 1-2. Therefore, the April 23, 2013 letter did not purport to be a denial of a CLIA application under 42 C.F.R. § 493.1844(b)(2). Further, the April 23, 2013 letter did not discuss the merits of Petitioner's application and did not provide notice of a right to seek reconsideration. Therefore, that letter does not comply with the basic requirements for an initial determination under 42 C.F.R. § 498.20(a)(1). Because there is no evidence that CMS issued an initial determination based on Petitioner's CLIA application, I conclude that Petitioner has no right to appeal the content of the April 23, 2013 letter under 42 C.F.R. § 493.1844(c).

Certain cases that are subject to the procedural regulations in 42 C.F.R. Part 498 include a request for reconsideration as the first step in the appeal process. *See* 42 C.F.R. § 498.5. When this level of appeal is required by the regulations, the provider or supplier must file a reconsideration request within 60 of receiving an initial determination and that request "must state the issues, or findings of fact with which the affected party disagrees, and the reasons for disagreement." 42 C.F.R. § 498.22. Further, on reconsideration, CMS will consider all of the evidence on which the initial determination was based as well as the evidence submitted by the provider or supplier on reconsideration. 42 C.F.R. § 498.24. If CMS issues a reconsideration determination adverse to the provider or supplier, then that determination must specify "the conditions or requirements of law or regulations that the affected party fails to meet, and informs the party of its right to a hearing." 42 C.F.R. § 498.25(a)(3). The reconsidered determination becomes binding unless the provider or supplier filed a timely request for an ALJ hearing. 42 C.F.R. § 498.25(b). An ALJ only has jurisdiction to hear an appeal when CMS has first issued a reconsidered determination. *Karthik Ramaswamy, M.D.*, DAB No. 2563, at 7 (2014). In upholding this interpretation of 42 C.F.R. Part 498, a federal district court stated the following:

> As explained in the preceding paragraphs, the [Department of Health and Human Services] regulations create a system of appellate rights and procedures regarding enrollment determinations. These procedures, as interpreted by the ALJ and DAB, require a reconsidered determination before any review of a[] [CMS] contractor's initial determination can occur. Both the ALJ and DAB found that [the CMS contractor] did not issue a reconsidered determination; instead it dismissed Ramaswamy's request as untimely.
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> . . . .

> According to Ramaswamy, the ALJ's and DAB's interpretation is improper. Specifically, Ramaswamy contends that "[a] supplier has a ***'right to reconsideration'*** to the extent that he 'files a written request . . . ***[w]ithin 60 days from receipt*** of the notice of initial determination . . . . Because [the CMS contractor] failed to address the merits of [Ramaswamy's] request for reconsideration in its response, [the CMS contractor] effectively denied [Ramaswamy's] right to reconsideration as explicitly required by 42 C.F.R. § 498.22." Further, by interpreting the regulations as depriving them of the authority to review [the CMS contractor's] actions absent a reconsidered determination, the ALJ and DAB effectively made a nullity of the right to reconsideration established under the regulations.
>
> Ramaswamy fails to show that the ALJ's and DAB's interpretation of the applicable regulations is not entitled to deference. The regulations establish a detailed set of procedures for enrollment, which includes procedures to be followed for exercising appeal rights. The ALJ and DAB found that this detailed scheme is exclusive—that if the regulations do not explicitly establish a right to appeal in a particular situation, no right to appeal exists in that situation. While this may not be the only possible interpretation of the regulations and while it may in certain situations be unfair, it is not plainly erroneous or inconsistent with the regulations.

Ramaswamy v. Burwell, 83 F. Supp.3d 846, 854 (E.D. Mo. 2015) (emphasis in original) (internal citations omitted).

In the present matter, when CMS denies CLIA certification to a laboratory, the laboratory must first request reconsideration and, after receiving an unsatisfactory reconsidered determination, may request a hearing before an ALJ. 42 C.F.R. § 493.1844(e)(1), (3). The emails that Petitioner provides are insufficient to establish that Petitioner sought reconsideration of the denial of a CLIA application or, most importantly, that CMS issued a reconsidered determination. *See* Petitioner's Response 8-10. Because there is no reconsidered determination in this case, Petitioner has no right to an ALJ hearing. Therefore, I dismiss Petitioner's request for hearing. 42 C.F.R. § 498.70(b).

III. Conclusion.

Petitioner filed an application to receive CLIA certification. CMS believes that it cannot process that application until Dr. Ali complies with the requirements imposed on him

when another laboratory that he owned, Sonali, was sanctioned. Because I conclude that CMS has not issued an initial determination denying the application and has not issued a reconsidered determination on that issue, Petitioner does not have a right to a hearing before an ALJ.

/s/
Scott Anderson
Administrative Law Judge