Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Kids Med (Delta Medical Branch)
Docket No. A-12-53
Decision No. 2471
August 14, 2012

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Kids Med (Delta Medical Branch) (KMDMB), a clinical laboratory in Elsa, Texas, appeals a January 24, 2012 decision by Administrative Law Judge (ALJ) Richard J. Smith, *Kids Med (Delta Medical Branch) (CLIA No. 45D0925763)*, DAB CR2492 (2011) (ALJ Decision). In that decision, the ALJ granted the Centers for Medicare & Medicaid Services' (CMS's) motion to dismiss KMDMB's request for a hearing to challenge the revocation of KMDMB's certificate under the Clinical Laboratory Improvement Amendments (CLIA). We affirm the ALJ Decision.

Applicable Law

Under CLIA, all laboratories that perform clinical diagnostic tests on human specimens must meet certain requirements and be federally certified. *See* Pub. L. No. 100-578, *amending* section 353 of the Public Health Service Act, *codified at* 42 U.S.C. § 263a. CLIA grants the Secretary of Health and Human Services (Secretary) broad enforcement authority, including the ability to suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more requirements for certification. 42 U.S.C. § 263a(i). The Secretary has delegated to CMS the authority to inspect, or to have its agents inspect, laboratories and to sanction laboratories that fail to comply with the certification requirements. *See generally* 42 C.F.R. Part 493, Subparts Q & R.

A laboratory that is dissatisfied with CMS's decision to suspend, limit, or revoke its CLIA certificate may request a hearing before an ALJ with the Departmental Appeals Board (DAB). 42 C.F.R. § 493.1844(a), (b). The request must be filed within 60 days of receipt of notice of the decision, unless the ALJ determines that there is good cause for extending the filing deadline. *Id.* § 498.40(a), (c). An ALJ may dismiss an untimely request on his or her own motion or the motion of a party. *Id.* § 498.70(c). A request for hearing must identify "the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees," and specify "the basis for contending that the findings and conclusions are incorrect." *Id.* § 498.40(b).

Case Background[1]

In September 2010, the Texas Department of State Health Services, acting as CMS's agent, conducted a recertification survey of KMDMB. Based on the findings from that survey, on March 9, 2011, CMS notified KMDMB by faxed letter to its owner-director, Dr. Wilfredo A. Aviles, that it had determined the facility was not in substantial compliance with several conditions of participation in the CLIA program. CMS explained in the letter that, effective March 14, 2011, it would suspend KMDMB's CLIA certificate and cancel KMDMB's approval to receive Medicare payments for its services. The March 9 letter further explained in two separate paragraphs that Dr. Aviles had 60 days to request a hearing before a DAB ALJ if he believed that CMS's determination was incorrect. In addition, the letter stated that if a hearing request was not received within 60 days, CMS would automatically revoke KMDMB's CLIA certificate. ALJ Decision at 2; CMS Ex. 1, at 4-5. The letter also warned that 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8) prohibit the owners, operators, and directors of laboratories that have had their CLIA certificates revoked from owning, operating, or directing another laboratory for at least two years from the date of revocation.[2] CMS Ex. 1, at 6.

In a letter dated March 14, 2011, Dr. Aviles contacted CMS. In his letter to CMS, which was written on MVP letterhead, Dr. Aviles admitted that "serious mistakes were made," but asked CMS to consider allowing KMDMC to at least continue providing "CLIA-waived tests." ALJ Decision at 2; P. Ex. 2.

On April 19, 2011, CMS sent a faxed letter to Dr. Aviles that acknowledged receipt of his letter but explained that CMS could not allow KMDMB to perform CLIA-waived tests. The letter also reminded Dr. Aviles that KMDMB's CLIA certificate would be automatically revoked on May 10, 2011 if Dr. Aviles did not file a hearing request within the 60-day period and referred Dr. Aviles to CMS's earlier March 9, 2011 letter for an explanation of the laboratory's appeal rights. ALJ Decision at 3; CMS Ex. 2, at 3-4. It is undisputed that Dr. Aviles did not file a hearing request before an ALJ by the May 9 deadline. Accordingly, CMS revoked KMDMB's CLIA certificate on May 10, 2011. Approximately a week later, CMS notified MVP, DMC, and MCC that it would be revoking their CLIA certificates in light of the revocation of KMDMB's certificate. ALJ Decision at 3; CMS Ex. 4.

[1] Background information is drawn from the ALJ Decision and the record before him and is not intended to substitute for his findings.

[2] At the time, Dr. Aviles owned at least three other CLIA-certified laboratories in the area served by KMDMB, namely Mid Valley Pediatrics (MVP), Donna Medical Clinic (DMC), and Mercedes Childrens Clinic (MCC).

On July 18, 2011, MVP, DMC, and MCC filed separate but substantively identical hearing requests with the DAB, in which they challenged the revocation of KMDMB's CLIA certificate. ALJ Decision at 3; Appellant Ex. 1.[3] On August 16, 2011, CMS moved for summary judgment in the three appeals, arguing that once KMDMB's revocation became administratively final, the other facilities' revocations were mandatory under 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8). ALJ Decision at 3-4.

On August 31, 2011, KMDMB filed with the DAB, and served on CMS, a document titled "Request for Hearing" in which it argued that Dr. Aviles's March 14 letter to CMS constituted a timely and complete request for hearing. In the alternative, KMDMB maintained that there was good cause for allowing it to file a request beyond the 60-day deadline. The following day, MVP, DMC, and MCC filed nearly identical responses to CMS's motions to dismiss, arguing that the revocation of KMDMB's CLIA certificate was not administratively final in light of Dr. Aviles's March 14 letter and KMDMB's August 31 filing. ALJ Decision at 4.

CMS subsequently moved to dismiss KMDMB's hearing request pursuant to 42 C.F.R. § 498.70(c), arguing that it was untimely filed and did not proffer any good cause for why the 60-day deadline should be extended. KMDMB opposed the motion and sought leave to amend Dr. Aviles's March 14 letter to cure any deficiencies so that the appeal could be perfected. The ALJ consolidated MVP, DMC, and MCC's appeals and stayed a decision in the consolidated case pending the disposition of KMDMB's hearing request. ALJ Decision at 4-5.

The ALJ Decision

The ALJ first determined that Dr. Aviles's March 14 letter to CMS was not a request for hearing under section 498.40. The ALJ next concluded that KMDMB failed to show good cause to be permitted to amend the letter to meet the requirements of section 498.40 or to extend the deadline for filing a request for hearing. Accordingly, the ALJ granted CMS's motion to dismiss KMDMB's appeal.

[3] The ALJ Decision discusses the contents of the other laboratories' hearing requests, which were filed with the ALJ in case nos. C-11-617, C-11-618, and C-11-619 (*see* ALJ Decision at 3), but were not part of the record in the instant case. KMDMB attached the requests to its Request for Review as Appellant's Exhibit 1. In the absence of an objection from CMS, we admit the requests into evidence solely for the purpose of making the record complete in this case since the ALJ addressed these documents in his decision. Our inclusion of these documents is not a determination that they are relevant to this case.

Standard of Review

The Board reviews a disputed finding of fact to determine whether the finding is supported by substantial evidence on the record as a whole, and a disputed conclusion of law to determine whether it is erroneous. Guidelines -- Appellate Review of Decisions of Administrative Law Judges in Cases Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and Related Statutes, *available at* http://www.hhs.gov/dab/divisions/appellate/guidelines/clia.html. The Board reviews a "good cause" finding under 42 C.F.R. § 498.40(c)(2) for abuse of discretion. *Waterfront Terrace, Inc.*, DAB No. 2320, at 5 (2010).

Analysis

1. The ALJ did not err in concluding that Dr. Aviles's March 14 letter was not a request for hearing.

KMDMB asserts on appeal, as it did before the ALJ, that Dr. Aviles's March 14 letter to CMS – which was sent to CMS within the 60-day window for filing an appeal – should be found to qualify as a hearing request. Request for Review (RR) at 2. The ALJ rejected this argument, and we find no error in his doing so.

The body of Dr. Aviles's letter reads in pertinent part:

> In regards to your imposition of sanction on the above medical facility, we understand its terms and are prepared to fully comply with the decisions set forth. We would, however, like for you to reconsider allowing us to at least provide our patients with continued care by performing only our CLIA-waived tests. We are very sorry and deeply apologize for the inconvenience and unforeseen turn of events. We did have a change of employees around the time of our survey and we acknowledge the facts that serious mistakes were made. We have been enrolled with the CLIA program since its beginning in 1988, and have never encountered a deficiency/sanction as serious as this. Mid Valley Pediatrics and Kids Med have always been in compliance with CLIA regulations. Mid Valley Pediatrics & Associates, along with other reputable businesses, strive to provide high quality medical care to our patients and our community. Again, for the above reasons, we hopefully request that you reconsider, and at least allow us to continue performing our simple CLIA-waived tests.

P. Ex. 2.

We note at the outset that the March 14 letter neither identified specific issues, findings of fact, and conclusions of law with which Dr. Aviles disagreed, nor specified any basis for disagreement, as required by 42 C.F.R. § 498.40(b). KMDMB does not contend before us that the March 14 letter conforms to the express content requirements of section 498.40(b), and it is unclear whether it made such a contention before the ALJ.[4] In any event, the ALJ did not base his ruling on failure to comply with section 498.40(b)'s content requirements. Instead, the ALJ concluded that, even disregarding the specific content requirements of section 498.40(b), the letter cannot be reasonably understood as an expression of disagreement with CMS's actions and an attempt to appeal them. ALJ Decision at 5.

On appeal before us, KMDMB argues the ALJ erroneously ignored certain phrases in the letter that indicated Dr. Aviles's intent to appeal CMS's determination. RR at 2-3. KMDMB also urges that the March 14 letter should be broadly construed as a hearing request because Dr. Aviles is not an attorney and did not have legal assistance at the time he drafted the letter. *Id*. at 4-5.

We agree with the ALJ that, even taking into account Dr. Aviles's non-attorney status, the March 14 letter cannot reasonably be read as expressing his intent to request a hearing to contest CMS's determination of March 9, 2011. ALJ Decision at 5-6, 7. As the ALJ accurately noted, in the March 14 letter Dr. Aviles acknowledged the proposed sanction, apologized for the facility's errors, and pleaded for some of KMDMB's testing procedures to be excepted from the sanction. *Id.* at 5-6. The letter does not use the word "hearing" or challenge the findings of noncompliance outlined in CMS's letter. Indeed, it is captioned "Re: Request to continue CLIA-Waived tests (only) at Kids Med (Delta Medical Branch) Elsa, Texas." P. Ex. 2. In addition, CMS's March 9 letter to Dr. Aviles explained in a section titled "Appeals Process" that any hearing request needed to be filed with the DAB and copied to CMS, as required by 42 C.F.R. § 498.40(a)(1). ALJ Decision at 5; CMS Ex. 1, at 6. Yet, Dr. Aviles sent the March 14 letter to CMS rather than to the Civil Remedies Division of the DAB, as CMS's March 9 letter clearly instructed him to do if he was dissatisfied with CMS's determination of noncompliance. P. Ex. 2.

We are similarly unconvinced by KMDMB's argument that the ALJ erroneously overlooked language in MVP, DMC, and MCC's hearing requests that, KMDMB maintains, supports the interpretation of Dr. Aviles's letter as a request for hearing. The ALJ noted that the other facilities challenged the revocation of KMDMB's CLIA

[4] In its response to CMS's motion to dismiss, KMDMB argued, "After closely examining the language of the March 14, 2011 letter in context with the existing factual circumstances, the requirements of 40 C.F.R. § 498.40(b) have clearly been met." But in the very next sentence KMDMB clarified, "Petitioner has always conceded that on its face, the letter may not appear to meet the strict requirements of 40 C.F.R. § 498.40(b)." P.'s Resp. to R.'s Motion to Dismiss at 7.

certificate on the merits in their hearing requests and did not assert that KMDMB had perfected its own appeal. ALJ Decision at 3. KMDMB asserts that the ALJ should have focused instead on the laboratories' contentions about why KMDMB's certificate should not have been revoked. According to KMDMB, the other facilities' arguments are evidence of KMDMB's "intent to reemphasize and narrow the focus of the language contained in the March 14, 2011 letter written by an unrepresented Dr. Aviles." RR at 9.

KMDMB cannot rely upon the hearing requests filed by MVP, DMC, and MCC on Agusut 31 to cure the deficiencies in Dr. Aviles's March 14 letter. These filings, made by separate entities long after the period for appealing KMDMB's revocation had expired, are not relevant to demonstrating a disagreement with the survey findings about KMDMB that Dr. Aviles nowhere expressed during the appeal period set out in KMDMB's revocation notice. We note that none of the hearing requests even mentions the March 14 letter, much less "reemphasizes" any points made in that letter.

Have carefully considered all of KMDMB's arguments, we find no error in the ALJ's conclusion that Dr. Aviles's letter did not effectuate a request for hearing.

2. The ALJ did not abuse his discretion in determining that KMDMB failed to establish good cause for allowing it to amend the letter or extending the deadline to file a request for hearing.

KMDMB also challenges the ALJ's determination that it failed to establish good cause for either amending Dr. Aviles's letter or extending the deadline for filing a hearing request. The Board "has never attempted to provide an authoritative or complete definition of the term 'good cause' in 42 C.F.R. § 498.20(c)(2)." *Brookside Rehab. & Care Center*, DAB No. 2094, at 7 n.7 (2007); *Wesley Long Nursing Center, Inc.*, DAB No. 1937, at 9 n.7 (2004); *Hillcrest Healthare, L.L.C.*, DAB No. 1879, at 5 (2003). As in *Brookside*, there is no need for us to decide exactly the scope of an ALJ's discretion under that section because we agree with the ALJ that the facts of this case do not show good cause under "any reasonable definition of that term." ALJ Decision at 10; *see also Brookside*, DAB No. 2094, at 7 n.7.

KMDMB argues that the ALJ improperly attributes to Dr. Aviles deliberate inaction as a tactical choice whereas Dr. Aviles allegedly "thought he had already made a request for an appeal" by virtue of his March 14 letter to CMS. RR at 11. It is unnecessary to delve into whether Dr. Aviles had in mind any strategic motive in not filing a hearing request. It suffices that we agree with the ALJ that Dr. Aviles (even as an unrepresented party) could not reasonably have believed when he sent CMS the March 14 letter that it was a request for an appeal. As discussed, nothing in its content or in Dr. Aviles's conduct demonstrates any intent to seek a hearing at that time.

Like the ALJ, we also do not see any evidence in the record that Dr. Aviles could have believed his March 14 letter effectuated a request for hearing. As the ALJ noted, CMS twice explained to Dr. Aviles that an appeal to an ALJ was available, what needed to be done when in order to request a hearing, and the consequences for KMDMB of the failure to avail itself of its appeal rights. ALJ Decision at 8. In its initial March 9 letter, CMS notified Dr. Aviles of the 60-day timeframe for filing a request for hearing. In a section titled "Appeal Rights," CMS also outlined the procedures to follow to make a request. CMS Ex. 1, at 7-8. CMS reiterated or referenced this same information again in its April 19th letter. CMS Ex. 2, at 3-4. These communications gave Dr. Aviles two clear notices of his right to request a hearing and the deadline to make such a request. *See Hillcrest Healthcare, L.L.C.*, DAB No. 1879, at 7 (finding no good cause for skilled nursing facility's failure to file timely hearing request where facility received "a clear notice of its right to request a hearing and the deadline for making such a request").

We also agree with the ALJ's statement that – "If Dr. Aviles had harbored any remaining notions that his March 14 letter had left CMS's determination or any part of its proposed sanctions in suspense or abeyance, the April 19 letter put an end to them." ALJ Decision at 8. As the ALJ correctly observed, CMS's April 19 letter made clear it interpreted Dr. Aviles's letter only as a request to be allowed to perform CLIA-waived tests, not as a request for hearing. ALJ Decision at 8. That letter explained: "CMS received your letter dated March 14, 2011. Unfortunately, CMS cannot allow your laboratory to perform waived testing under a revocation . . ." *Id.* at 3. CMS also reminded KMDMB about the appeal deadline and what KMDMB needed to do if it wished to challenge CMS's March 9 determination. Further, the letter did not suggest that the imposition of sanctions was on hold pending a resolution by an ALJ. On the contrary, it directed, "You must cease ALL patient testing." *Id.* at 4. Even assuming the April 19 letter contradicted Dr. Aviles's understanding of the impact of his letter to CMS, he was not left without recourse. Both CMS's initial March 9 letter and its April 19 response letter provided the name, phone number, and email address of a CMS employee to contact with any questions. *Id.*; CMS Ex. 1, at 7. Yet nothing in the record suggests that Dr. Aviles or any other representative of KMDMB made any effort to contact CMS beyond sending the March 14th letter.

Moreover, as the ALJ noted, CMS's April 19 letter was not the only "warning flag" that signaled Dr. Aviles's March 14 letter had not preserved KMDMB's appeal rights. ALJ Decision at 8-9. On May 19, CMS notified MVP, DMC, and MCC via letters addressed to Dr. Aviles that it was revoking their CLIA certificates "because of" KMDMB's revocation. CMS Ex. 4, at 3, 8, 13. On August 16, CMS moved to dismiss those laboratories' requests for review based on the finality – in the absence of an appeal – of KMDMB's revocation. ALJ Decision at 9. Yet KMDMB did not take any action to verify that it had perfected its appeal rights until August 31, 2011, when at last it filed an official request for review. As the ALJ correctly pointed out, the hearing request was filed 25 weeks after CMS's initial notification and 16 weeks after the period for filing a

request had expired. ALJ Decision at 9. In light of the many indications prior to August 31 that Dr. Aviles's letter had not been construed as a request for hearing, we agree with the ALJ that there is no reasonable basis for excusing KMDMB's inaction.

In a further effort to establish good cause, KMDMB asserted before the ALJ, and continues to maintain here, that the errors leading to the revocation were isolated and attributable to a single, new employee who was later reassigned to less responsible tasks. KMDMB also argues that, because the revocation of its certificate causes a total of four facilities to lose their certificates, the impact on the community is disproportionately harmful. RR at 11-12. Even if true, these contentions do not speak to KMDMB's failure to timely exercise its appeal rights and so do not constitute grounds for finding good cause under any "reasonable definition" of that term.

Conclusion

For the reasons stated above, we find that the ALJ did not abuse his discretion in dismissing KMDMB's hearing request and we affirm the dismissal.

/s/
Sheila Ann Hegy

/s/
Leslie A. Sussan

/s/
Stephen M. Godek
Presiding Board Member