Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Kids Med (Delta Medical Branch)
(CLIA No. 45D0925763),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-11-749

Decision No. CR2492

Date: January 24, 2012

DECISION

This matter is before me on CMS's Motion to Dismiss filed on September 14, 2011. For the reasons set out in the discussion below, I GRANT the CMS Motion. But the procedural history of this case is unusual and somewhat complex; moreover, this appeal is related to other litigation now before me. Thus, a review of the events in this case and a brief discussion of events in that other litigation will be helpful in explaining how I have applied certain principles well-established in this forum to the merits of the CMS Motion.

I. PROCEDURAL HISTORY

Petitioner Kids Med (Delta Medical Branch) (KMDMB) is a clinical medical laboratory located in Elsa, Texas, a small community in the lower Rio Grande Valley approximately halfway between McAllen and Harlingen. Until the events that form the basis of this appeal, KMDMB participated in the Medicare and Texas Medicaid programs and held a CLIA certificate under the provisions of the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a *et seq*. KMDMB is owned by W. A. Aviles,

M.D. Dr. Aviles at that time owned at least three other CLIA-certified facilities in that general area: Mid Valley Pediatrics (MVP), Donna Medical Clinic (DMC), and Mercedes Childrens Clinic (MCC).

On September 22, 2010, surveyors from the Texas Department of State Health Services (TDSHS) conducted a compliance survey of KMDMB and found it out of substantial compliance with several conditions of participation in the CLIA program. TDSHS informed CMS of its findings and CMS adopted them. On March 9, 2011, CMS wrote to KMDMB and notified it of those findings and of the sanctions CMS would impose as a result. CMS told KMDMB that the laboratory's CLIA certificate would be suspended effective March 14, 2011, and that its approval to receive payments under Medicare and the Texas Medicaid program would be cancelled as of that date. The CMS notice contained a separate section, set off by a heading captioned "Appeals Process," with a clear and detailed explanation of KMDMB's appeal rights, including a citation to 42 C.F.R. § 493.1844, the regulation governing an appeal, an explicit mention of the 60-day deadline for perfecting an appeal, a statement of the content requirements for a satisfactory request for hearing on appeal, and the addresses to which a request for hearing must be sent.

The CMS notice of March 9, 2011 contained additional warnings to KMDMB that are of significance to this appeal. The CMS notice cautioned KMDMB that its CLIA certificate — merely suspended as of March 14, 2011 — would be revoked completely on May 10, 2011 unless KMDMB had filed a request for hearing to contest the CMS action by May 9, 2011. Because CMS sent its March 9 notice to KMDMB by facsimile transmission on March 9, 2011, and because KMDMB received the facsimile transmission on the date it was sent, CMS apparently calculated the 60-day appeal deadline established by 42 C.F.R. § 498.40(a)(2) to end on May 9, 2011.

The CMS notice contained yet another significant warning to KMDMB and Dr. Aviles. Although it did not mention MVP, DMC, or MCC by name, the CMS notice explicitly cautioned that certain statutory and regulatory provisions — 42 U.S.C. § 263(a)(i)(3) and 42 C.F.R. § 493.1840(a)(8) — prohibit the owner of a laboratory with a revoked CLIA certificate from owning, operating, or directing another CLIA laboratory for a period of two years.

KMDMB's immediate response to the CMS notice was not the filing of a request for hearing. Instead, Dr. Aviles wrote to CMS on March 14, 2011 on MVP letterhead and acknowledged the CMS notice, expressed that "we understand its terms and are prepared to fully comply with the decisions set forth," offered an explanation of the lapses and "serious mistakes" at KMDMB, and ended with the "request that you reconsider, and at least allow us to continue performing our simple CLIA-waived tests. Please advise."

CMS responded to Dr. Aviles and KMDMB in a letter dated and sent by facsimile transmission on April 19, 2011. That letter told Dr. Aviles and KMDMB that "CMS cannot allow your laboratory to perform waived testing." The letter enjoined: "You must cease **ALL** patient testing."[1] The CMS letter repeated the warning about the impending revocation of KMDMB's CLIA certificate on May 10, 2011 if an appeal were not filed by May 9, 2011, and explicitly reminded KMDMB and Dr. Aviles that a statement of KMDMB's appeal rights could be found in the CMS notice of March 9.

May 2011 came and went without further action on the part of Dr. Aviles or KMDMB. In the absence of any such action toward perfecting an appeal, the CMS determination took full effect and KMDMB's CLIA certificate was revoked on May 10, 2011. But as CMS had warned in its March 9 notice, other consequences immediately followed the KMDMB revocation.

CMS had warned Dr. Aviles that the owner of a laboratory with a revoked CLIA certificate is prohibited from owning, operating, or directing another CLIA laboratory for a period of two years. As I have noted above, Dr. Aviles was at the time the owner of MVP, DMC, and MCC. On May 19, 2011, CMS sent separate notices to MVP, DMC, and MCC that the three laboratories' CLIA certificates would be revoked effective July 20, 2011 if a request for hearing were not received by July 19, 2011. CMS explained that its determination was based on the revocation of KMDMB's CLIA certificate on May 10, 2011. The CMS notices repeated in essentially-identical language the explanation of appeal rights and procedures that had been given to KMDMB on March 9.

MVP, DMC, and MCC filed substantially-identical requests for hearing on July 18, 2011. MVP's appeal was docketed as C-11-617; DMC's was docketed as C-11-618, and MCC's was docketed as C-11-619. Each filing was confirmed by my standard Acknowledgment and Initial Docketing Order on July 20, 2011. Each of the three laboratories admitted in its request that the revocation of its CLIA certificate derived from the revocation of KMDMB's and sought to defend its own certificate by challenging CMS's revocation of KMDMB's certificate on the merits, although that challenge went to only one of several instances of noncompliance with which KMDMB had been cited. None of the three requests for hearing asserted or appeared to assume that KMDMB had ever perfected an appeal on its own, and as of July 18, 2011, that was the case: KMDMB had neither sought nor attempted to seek relief in this forum from the CMS determination of March 9, 2011.

CMS answered the MVP, DMC, and MCC appeals on August 16, 2011 with identical filings in C-11-617, C-11-618, and C-11-619. CMS filed a Motion for Summary

[1] Here, as elsewhere in the following pages, I have replicated the original text's use of emphasis, underlining, or bold type when quoting from material in this record, or from pleadings in C-11-617, C-11-618, or C-11-619.

Judgment in each case, noting, *inter alia*, that once the revocation of KMDMB's CLIA certificate became final, the revocation of MVP's, DMC's, and MCC's CLIA certificates was mandated as a matter of law. 42 U.S.C. § 263a(i)(3); 42 C.F.R. § 493.1840(a)(8); see *Sol Teitelbaum, M.D.*, DAB No. 1849 (2002). Each of the CMS Motions discussed the finality of the KMDMB revocation in this language: "Wilfredo A. Aviles failed to file a request for a hearing in that enforcement action. As a result, CMS' determinations and imposed sanctions [with reference to KMDMB] are administratively final and cannot be appealed or challenged."

Although not a party to C-11-617, C-11-618, or C-11-619, KMDMB responded to the CMS Motions for Summary Judgment in two ways. First, on August 31, 2011, KMDMB sent this forum what purported to be a request for hearing challenging the CMS determination of March 9, 2011. The purported request was signed by counsel associated with the law firm that appeared for MVP, DMC, and MCC in their appeals. Interestingly, KMDMB's letter asserts among other things that "A Timely and Complete Request for Hearing was filed March 9, 2011." What KMDMB meant by that statement is not clear, but what it did assert in the remainder of its letter is that Dr. Aviles' March 14 letter to CMS was, in fact, a request for hearing compliant with 42 C.F.R. § 498.40. In the alternative, however, KMDMB argued that good cause exists for extending the time for filing so as to allow its August 31 letter to serve as a timely request. The KMDMB letter made no attempt to meet the content requirements of 42 C.F.R. § 498.40(b). This request for hearing was docketed as C-11-749, and it is this request for hearing that forms the basis of this litigation.

Once KMDMB had sent its August 31 letter in C-11-749, the second part of its response to the CMS Motions for Summary Judgment in C-11-617, C-11-618, and C-11-619 was given effect. In each of those cases, the appealing laboratory resisted CMS's Motion by filing on September 1, 2011 its Response to the CMS Motion for Summary Judgment arguing that because KMDMB had filed its March 14 letter and its August 31 letter, the revocation of KMDMB's CLIA certificate was not administratively final. A week later, on September 9, 2011, each laboratory filed its own Motion for Summary Judgment advancing essentially the same argument.

Now, it may serve the interests of clarity to pause here briefly to explain, and then set aside, developments in the separate appeals of MVP, C-11-617; DMC, C-11-618; and MCC, C-11-619. The parties have debated the issues I have outlined above at some length in those cases, and have done so in terms identical among the three appeals. But by October 2011 it had become apparent to all concerned that those three appeals addressed common, identical issues of fact and law, and that all three depended on the outcome of this case for their final resolution. Accordingly, by my Order of October 18, 2011 I consolidated the three cases as C-11-619, dismissed C-11-617 and C-11-618, and stayed C-11-619 pending the disposition of this case. That disposition is, of course, the subject of this Decision.

The procedural history of this case nears completion. On September 14, 2011, CMS filed its Motion to Dismiss KMDMB's hearing request in this case; in its Motion, CMS argued that Dr. Aviles' letter of March 14 did not constitute a request for hearing, and that KMDMB had not shown good cause for extending the deadline for KMDMB to file such a request. KMDMB filed two pleadings on October 3, 2011: a Motion to Request Leave to Amend Hearing Request, and a Response to CMS's Motion to Dismiss. The Motion to Request Leave to Amend Hearing Request sought permission to amend Dr. Aviles' March 14, 2011 letter in order that it might comply with 42 C.F.R. § 498.40(b) in order to "avoid complete depravation" of KMDMB's hearing rights, but did not set out the particulars by which it would accomplish compliance with the content requirements of that regulation. The Response maintained KMDMB's assertions that Dr. Aviles' letter was a valid and sufficient request, but went on to urge in the alternative that it should be permitted to amend that letter. Implicit in KMDMB's position is the notion that it has shown good cause for whatever extension of time it may need to accomplish full compliance with 42 C.F.R. § 498.40(a) and (b). The final pleading was CMS's October 18, 2011 Reply to Petitioner's Response to Respondent's Motion to Dismiss.

II. DISCUSSION

The procedural history set out above may border on the baroque, but at its heart lies one rather straightforward question: was Dr. Aviles' letter of March 14, 2011 a request for hearing compliant with the terms of 42 C.F.R. § 498.40? Depending on the answer to that question, then another question presents itself: if Dr. Aviles did not perfect KMDMB's appeal with his March 14 letter, then does good cause exist in this record to allow KMDMB *either to amend the letter* and bring it into compliance with 42 C.F.R. § 498.40 *or to extend the deadline* for filing KMDMB's request for hearing so that its August 31, 2011 filing can be considered timely?

A. Was Dr. Aviles' letter of March 14, 2011 a request for hearing compliant with the terms of 42 C.F.R. § 498.40?

This record demonstrates quite clearly that Dr. Aviles' letter of March 14, 2011 was not intended by its author as a request for hearing. Even with the specific content requirements of 42 C.F.R. § 498.40(b)(1) and (2) put momentarily aside, and even disregarding the requirement at 42 C.F.R. § 498.40(a)(1) that a valid request for hearing must be filed in the correct forum by mailing it to the correct address, Dr. Aviles' letter cannot be reasonably understood to be the expression of "a laboratory dissatisfied with the suspension, limitation, or revocation of its CLIA certificate" and seeking appellate review of such action. See 42 C.F.R. § 493.1844(f). It can be reasonably understood only thus: as the expression of Dr. Aviles' and KMDMB's acceptance of the TDSHS findings, as an *apologia* for the several lapses in KMDMB's compliance, as an acknowledgment that the proposed sanction would be imposed, and as a plea that some of

its testing procedures — and of Texas Medicaid's payment for them — might be excepted from the scope of the sanction.

This is not a situation in which the teachings of *The Carlton at the Lake*, DAB No. 1829 (2002) and *Alden Nursing Center-Morrow*, DAB No. 1825 (2002) can be invoked or relied upon. Those cases depended for their whole logical integument on the obvious notion that those cited facilities disagreed with the factual and legal bases of their citations and were trying to appeal and reverse the CMS determinations based on those citations. Here, there is no danger that in reading Dr. Aviles' letter I might "lightly conclude that a petitioner has failed in its effort to take advantage of its opportunity for a hearing." *The Carlton at the Lake*, DAB No. 1829, at 8. It requires no hyper-technical comparison of his letter with the regulations to find and conclude, as I do here, that Dr. Aviles expressed no wish or intention to take advantage of his opportunity for a hearing. Line by line, Dr. Aviles' letter accepts, rather than contests, the results of the TDSHS survey and the CMS determination.

The letter begins by stating "[i]n regards to your imposition of sanction on the above medical facility [KMDMB], we understand its terms and are prepared to fully comply with the decisions set forth." After a sentence requesting CMS to "reconsider allowing us to at least provide our patients with continued care by performing only our CLIA-waived tests," the letter expresses regret and an apology, and then offers this statement: "We did have a change of employees around the time of our survey and we acknowledge the fact that serious mistakes were made." The letter goes on to recount KMDMB's long history of CLIA certification and asserts that it has "never encountered a deficiency / sanction as serious at this. [MVP] and [KMDMB] have always been in compliance with CLIA regulations." The letter ends with the repeated request that CMS reconsider allowing KMDMB to "continue performing our simple CLIA-waived tests."

KMDMB has labored mightily to cast this letter as an inartfully-drafted document written by a non-attorney, and urges that it should be understood as "contending that CMS' determination was incorrect" and as seeking "ideally that the imposition of sanctions be declared improper." Neither those words nor any like them can be found in Dr. Aviles' letter, and to suggest that Dr. Aviles meant such things by the words he wrote is recklessly to distort both the plain meaning of his letter and the broader sense it conveys: acceptance of the TDSHS findings and the CMS determination, and the acknowledgment that "serious mistakes were made" and that "we . . . are prepared to fully comply with the decisions set forth." And although Dr. Aviles may not have been trained in legal matters, he could rely on over two decades of experience in dealing with CMS, TDSHS, and CLIA requirements: his letter points out that "[w]e have been enrolled with the CLIA program since its beginning in 1988, and have never encountered a deficiency/ sanction as serious as this." His twenty-plus years of dealing with CLIA regulations and compliance surveys means, at the very least, that he was hardly a *naif* overwhelmed by impending government action: providers such as Dr. Aviles and KMDMB are charged

with knowledge of the regulations governing program participation, and are assumed to understand both the importance of the notice of appeal rights set out in the CMS notice and of the necessity for careful, timely compliance with it in filing a hearing request. *Cary Health and Rehabilitation Center*, DAB No. 1771, at 20 n.7 (2001); *Brookside Rehabilitation and Care Center*, DAB CR1541 (2006), aff'd, *Brookside Rehabilitation and Care Center*, DAB No. 2094 (2007).

Thus, in summarizing this record and the light it sheds on Dr. Aviles' letter of March 14, 2011, the evidence shows this: Dr. Aviles and KMDMB were long-time participants in the CLIA program; the CMS letter of March 9, 2011 was clear and unequivocal in advising Dr. Aviles and KMDMB of both their appeal rights and the procedures they must follow to perfect an appeal; the CMS letter also warned Dr. Aviles and KMDMB of the serious consequences to which MVP, DMC, and MCC were exposed if the KMDMB sanction became final; in writing his letter of March 14, Dr. Aviles had the benefit of extensive experience in dealing with CMS, TDSHS, and the mechanisms of CLIA compliance enforcement; and no reasonable reading of Dr. Aviles' March 14 letter suggests his or KMDMB's intention to appeal the CMS determination of March 9, 2011.

Dr. Aviles' letter of March 14, 2011 was not a request for hearing compliant with the terms of 42 C.F.R. § 498.40. See *Apple Home Health Services*, DAB No. 2188 (2008).

B. Does good cause exist in this record to allow KMDMB to amend Dr. Aviles' March 14, 2011 letter and bring it into compliance with 42 C.F.R. § 498.40, or to extend the deadline for filing KMDMB's request for hearing so that its August 31, 2011 filing can be considered timely?

In cases where a request for hearing has not been timely filed, the affected party or an entity acting on its behalf may seek an extension of the usual 60-day deadline. 42 C.F.R. § 498.40(c)(1). KMDMB did so, in effect, with the two pleadings it filed on October 3, 2011, although neither pleading makes specific reference to that precise regulation or explains what KMDMB believes to be the "good cause" standard it must meet before I should exercise my discretion to grant the extension pursuant to 42 C.F.R. § 498.40(c)(2).

The definition of "good cause" in this forum is considerably broader than it may once have appeared. It is no longer limited to a showing of circumstances beyond the ability of a party to control, as in *Hospicio San Martin*, DAB No. 1554 (1996). But whatever it may be in the abstract, the specific facts relied on to establish "good cause" in a particular case must fit within a "reasonable definition of that term." *Brookside Rehabilitation and Care Center*, DAB No. 2094, at 7, n.7. It is impossible to view the facts in this case as fitting within any reasonable definition of "good cause," for the circumstances of this case between March 2011 and August 31, 2011 point to little other than deliberate inaction, a course followed as a tactical choice, by KMDMB.

The exchange of letters between CMS and Dr. Aviles in March 2011 led to CMS's letter to Dr. Aviles on April 19, 2011. The principal message of that letter was to make Dr. Aviles aware beyond the possibility of misunderstanding that KMDMB would not be permitted to conduct "CLIA-waived" testing. Its language could not have been clearer: "You must cease **ALL** patient testing." 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. The CMS letter included language that read: "This is to inform you, CMS has imposed the following sanctions effective **March 14, 2011** . . . ." The letter reminded Dr. Aviles and KMDMB of the approaching revocation on May 10, 2011. It reminded Dr. Aviles and KMDMB that the deadline for an appeal was approaching: "If a request for hearing is not received by **May 9, 2011** . . . ." And the CMS letter also left no room for doubt about what Dr. Aviles and KMDMB must do if they wished to challenge the CMS action. The April 19 CMS letter noted: "Please refer to our March 9, 2011 letter for your appeal rights" and the next paragraph provided a telephone number and email address to which Dr. Aviles could address any questions about the administrative aspects of the action.

The CMS letter of April 19 was sent by facsimile transmission and was received by Dr. Aviles and KMDMB the same day. Thus, Dr. Aviles and KMDMB still had 20 days left of the 60-day appeal period within which to perfect an appeal, and had during the first 40 days twice received explicit warnings and advice. The warnings of consequences to KMDMB, and to MVP, DMC, and MCC were clear and unambiguous, and they were ignored twice. The advice concerning the availability of an appeal and the method to be followed in perfecting one was simple and straightforward, and it was ignored twice.

It is not at all clear how KMDMB could have been ignorant of the suspension of its CLIA certificate after March 14, 2011, since its payments for services under the Texas Medicaid program ceased then and it still had almost seven weeks of its appeal period left. But if that much is unclear, then it is even more difficult to understand how KMDMB could have been unaware that its CLIA certificate had been revoked on May 10 once MVP, DCM, and MCC received the CMS notices of May 19, 2011. Yet KMDMB took no action to resuscitate its appeal rights then. If it had, it could have cast itself as the faultless victim of human error, trying earnestly to correct the error at the very first opportunity, a mere 10 days late. Instead, and for reasons of its own, it made the tactical choice to do nothing until the last days of the appeal period for MVP, DCM, and MCC, and then to do so obliquely. The July 18, 2011 requests filed by those three laboratories acknowledged that KMDMB's CLIA certificate had been revoked but argued that the revocation was unwarranted. The July 18 requests for hearing were filed nine weeks after the expiration of KMDMB's appeal deadline.

There is absolutely no reference in any of the three July18 requests for hearing that would explain or justify the absence of a perfected appeal by KMDMB, but once the filings had been acknowledged in the normal course of this forum's official business by my Orders

of July 20, 2011, yet another warning flag would have been obvious to KMDMB, MVP, DMC, and MCC: if KMDMB had perfected an appeal, where was the Acknowledgment and Initial Docketing Order so indicating?

If KMDMB was troubled by the absence of such an Order, it spent the next four weeks doing nothing to address the trouble. During that time it enjoyed again a chance to revive its appeal, but declined to do so. By August 16, 2011, KMDMB's right to appeal had been forfeit for 14 weeks. And on August 16, 2011 CMS filed its Motions for Summary Judgment in the MVP, DCM, and MCC appeals, relying on the finality — in the absence of an appeal — of the revocation of KMDMB's CLIA certificate.

If some reasonable definition of good cause might excuse KMDMB's failure to file a request for hearing through August 16, no "reasonable definition of that term" could excuse KMDMB's inaction beyond that date. But in spite of the array of warnings and cautions that had been obvious to KMDMB since March 9, and in the face of the explicit assertions in the CMS Motions of August 16 that no appeal had been filed, KMDMB did nothing until August 31, 2011. Then, 25 weeks after the CMS notice of March 9, and 16 weeks after its appeal period had expired, KMDMB filed its request for hearing.

No reasonable definition of the term "good cause" as it is employed by 42 C.F.R. § 498.40(c)(2) can compass KMDMB's inaction. There is no possibility that it was confused or misled by CMS at any point or on any issue. There is no realistic possibility that KMDMB was unaware that the action against its CLIA certificate had proceeded finally to revocation. By May 19, 2011 Dr. Aviles and KMDMB were on notice not only that the KMDMB certificate had been revoked because no appeal had been filed, but were also on notice that the collateral results of that revocation were moving forward in the absence of KMDMB's appeal. By July 20, 2011 the absence of acknowledgment and docketing papers in a supposed appeal by KMDMB gave further warning that no appeal was pending. The failure of KMDMB to perfect an appeal was made an explicit part of CMS's August 16 Motions in the MVP, DMC, and MCC appeals. This inaction by KMDMB over an extended period cannot be understood as lapses or mistakes. It can be understood only as the result of tactical choices, beginning with Dr. Aviles' letter of March 14, 2011.

This record does not support speculation as to what may have driven those tactical choices. It is clear, however, that all four of Dr. Aviles' Medicare- and Medicaid-participating laboratories are situated quite close to one another, with MVP, DMC, and MCC all within 10 miles of KMDMB and less than that from one another. It is at least conceivable that MVP, DMC, and MCC were able briefly to take over the testing that KMDMB was no longer allowed — and being paid by Medicare and Texas Medicaid — to do. Although there may be many other legitimate explanations, that scenario would explain why KMDMB did nothing until MVP's, DMC's, and MCC's CLIA certificates and Texas Medicaid approvals were revoked. But this record shows only geography and

a chronological sequence, and will carry speculation no further. What this record does not show is good cause, under "any reasonable definition of that term," to allow KMDMB to amend the letter and bring it into compliance with 42 C.F.R. § 498.40, or to extend the deadline for filing KMDMB's request for hearing so that its August 31, 2011 filing can be considered timely. Accordingly, I decline to do so and DENY KMDMB's October 3, 2011 Motion to Request Leave to Amend Hearing Request.

III. CONCLUSION

For all of the reason set out above, I find and conclude that: (1) Dr. Aviles' letter of March 14, 2011 was not a request for hearing as that term is contemplated by 42 C.F.R. § 493.1844(f) and 42 C.F.R. § 498.40; (2) KMDMB has not shown good cause to be permitted to amend Dr. Aviles' letter; (3) KMDMB has not shown good cause for the extension of the deadline for filing a request for hearing; and (4) KMDMB's August 31, 2011 request for hearing is untimely and must be dismissed pursuant to 42 C.F.R. § 498.70(c).

Accordingly, KMDMB's Motion to Request Leave to Amend Hearing Request is DENIED. The CMS Motion to Dismiss filed September 14, 2011 must be, and it is, GRANTED. On the authority of 42 C.F.R. § 498.70(c), KMDMB's August 31, 2011 request for hearing, and this appeal, are DISMISSED.

/s/
Richard J. Smith
Administrative Law Judge