Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Mercedes Children's Clinic/Mercedes Kids Med,

Petitioner,

v.

Centers for Medicare and Medicaid Services.

Docket No. C-11-619 (Consolidated)

Decision No. CR2614
Date: September 18, 2012

DECISION

This matter is before me on the CMS Motions for Summary Judgment filed on August 16, 2011 in the three separate appeals consolidated into this case and stayed by my Orders of October 18, 2011 and April 6, 2012. For the reasons set out in the discussion below, I GRANT the CMS Motions. But because the procedural history of this case is somewhat complex, a review of this case's history and a brief discussion of events in another related appeal will be helpful in explaining why I am now able to address the merits of the CMS Motions, and the rationale behind my decision to grant them. The facts I recite below are fully established in the pleadings and documents submitted by the parties. There are no genuine disputes as to any of the facts material to this decision.

1. Prodedural History:

The procedural history of this appeal begins with a laboratory not an actual party to it. Kids Med (Delta Medical Branch) (KMDMB) is a clinical medical laboratory located in Elsa, Texas. Until May 2011, 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 all relevant times also owned at least three other CLIA-certified medical laboratories in that general area: Mid Valley Pediatrics (MVP), Donna Medical Clinic (DMC), and Mercedes Children's Clinic/Mercedes Kids Med (MCC). Those three additional clinical laboratories — MVP, DMC, and MCC — are the Petitioners in this consolidated appeal.

In September 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. On March 9, 2011, CMS wrote to KMDMB and notified it of those findings and of the sanctions CMS would impose as a result. Those sanctions included the proposed revocation of KMDMB's CLIA certificate. The CMS notice explained KMDMB's appeal rights and specifically mentioned the 60-day deadline for perfecting an appeal.

The CMS notice of March 9, 2011 conveyed another significant warning to 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. § 263a(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 did not timely appeal the CMS notice. When KMDMB did attempt to challenge the CMS action in this forum on August 31, 2011, its request for hearing was docketed as C-11-749. CMS successfully sought the dismissal of KMDMB's request for hearing as untimely. The details of that litigation, and of my reasoning in granting the CMS Motion to Dismiss in that case, are set out fully in *Kids Med (Delta Medical Branch) (CLIA No. 45D0925763)*, DAB CR2492 (January 24, 2012). The Departmental Appeals Board (Board) affirmed my decision to dismiss KMDMB's appeal in *Kids Med (Delta Medical Branch)*, DAB No. 2471 (August 14, 2012).

The effect of my decision and the Board's affirmation of it has been to establish the revocation of KMDMB's CLIA certificate as final effective May 10, 2011. Thus, as of May 10, 2011, Dr. Aviles was the owner of a laboratory — KMDMB — with a revoked CLIA certificate, and was at the same time the owner of at least three other CLIA-certified laboratories, MVP, DMC, and MCC.

Now, it will be recalled that on March 9, 2011, CMS had warned Dr. Aviles that the owner of a laboratory with a revoked CLIA certificate is prohibited by statute from owning, operating, or directing another CLIA laboratory for a period of two years. On May 19, 2011, CMS sent separate notices to MVP, DMC, and MCC declaring 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 effective May 10, 2011.

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 appeal was docketed as C-11-618, and MCC's appeal was docketed as C-11-619. Each of the three laboratories noted 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.

CMS addressed 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 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." CMS Motions for Summary Judgment, at 10.

In each of those three 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 the revocation of KMDMB's CLIA certificate had not yet become administratively final. A week later, on September 9, 2011, each laboratory filed its own Motion for Summary Judgment advancing essentially the same argument.

The parties have argued at some length in those cases the issues I have outlined above, 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 — MVP in C-11-617, DMC in C-11-618 and MCC in C-11-619 — agreed on all material facts, addressed common, identical matters of fact and issues of law, and depended on the outcome of the litigation in C-11-749 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 C-11-749. That stay was extended by my Order of April 6, 2012.

The Order of April 6, 2012 contained other important provisions. While staying these proceedings during the pendency of KMDMB's appeal to the Board, the Order also provided for measures to be taken once the Board had ruled. Specifically, the parties were notified that if the Board's decision affirmed my dismissal of KMDMB's appeal, they "must, within 20 days, submit any additional briefing, argument, and authorities to address the motions for summary disposition now pending in this consolidated case."

The Board's decision in DAB No. 2471 was issued August 14, 2012. On September 12, 2012 CMS and the three individual Petitioners all confirmed that they had no further briefing, argument, or authorities to submit.

2. Discussion:

The coda to this procedural history is a straightforward question: once the revocation of KMDMB's CLIA certificate became final, did Dr. Aviles' ownership of MVP, DMC, and MCC mandate the revocation of their CLIA certificates? The unambiguous terms of 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), and the interpretation of those provisions by the Administrative Law Judges of this forum and by the Board, answer that question in the affirmative. Once KMDMB's CLIA certificate was revoked, Dr. Aviles' ownership of MVP, DMC, and MCC mandated that CMS revoke those laboratories' CLIA certificates.

The terms of 42 U.S.C. § 263a(i)(3) are plain, and the statute's language is mandatory:

> No person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section. The certificate of a laboratory which has been excluded from participation under the medicare program under title XVIII of the Social Security Act [42 U.S.C. § 1395 et seq.] because of actions relating to the quality of the laboratory shall be suspended for the period the laboratory is so excluded.

That plain and mandatory language is repeated, albeit in terms that might suggest some discretion on CMS's part, in the implementing regulation at 42 C.F.R. § 493.1840(a)(8):

> (a) *Adverse action based on actions of the laboratory's owner, operator or employees.* CMS may initiate adverse action to suspend, limit or revoke any CLIA certificate if CMS finds that a laboratory's owner or operator or one of its employees has—
>
> (8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. (This provision applies only to the owner or operator, not to all of the laboratory's employees.)

Whether mandatory or discretionary, however, the regulatory language cited above has been relied upon consistently, and has been understood by the Board unambiguously, to require the revocation of a laboratory's CLIA certificate in cases like this one:

> In adopting this regulation, CMS's predecessor agency stated that it had "no choice but to implement" the statutory provision "that the owner or operator of a laboratory that has had its certificate revoked may not own or operate a laboratory for two years after the revocation of the CLIA certificate of the initially sanctioned laboratory." 57 Fed. Reg. 7218, 7227 (Feb. 28, 1992).

Southlake Emergency Care Center, DAB No. 2402, at 2 (2011). See also *Evette Elsenety, M.D., et al.*, DAB CR779 (2001), *aff'd*, *Evette Elsenety, M.D., et al.*, DAB No. 1796 (2001).

The Board's decision in *Southlake* provides a virtual template for my decision here. In *Southlake*, the appeal involved two laboratories, Coppell and Southlake, that once were CLIA-certified. Both were owned by one C. J. O'Hearn, M.D. When CMS found Coppell noncompliant with condition-level CLIA requirements and proposed revocation of Coppell's CLIA certificate, Coppell did not appeal. The revocation of Coppell's certificate became final. CMS then notified Dr. O'Hearn that Southlake's CLIA certificate was to be revoked. Southlake did perfect an appeal from that action, and sought to defend its own CLIA certificate by challenging the revocation of Coppell's CLIA certificate. Relying on 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), Administrative Law Judge J. Grow granted summary judgment in CMS's favor, thus affirming the revocation of Southlake's certificate. *Southlake Emergency Care Center (CLIA # 45D1021990)*, DAB CR2300 (2011). The Board affirmed, and although its analysis of the issues before it included other matters not present in this case, its discussion of the two-year ban on Southlake's CLIA participation leaves no room at all for doubt that the uncontested facts of this case — that is, the fact of Dr. Aviles' ownership of KMDMB, MVP, DMC, and MCC, and the fact of the final and affirmed revocation of KMDMB's CLIA certificate — require the revocation of MVP's, DMC's, and MCC's CLIA certificates as a matter of law.

3. <u>Conclusion</u>:

For all of the reason set out above, I find and conclude that: **(1)** Kids Med (Delta Medical Branch) (KMDMB) is a clinical medical laboratory owned by W. A. Aviles, M.D.; **(2)** until May 10, 2011, 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*.; **(3)** Dr. Aviles at that time owned at least three other CLIA-certified medical laboratories in that general area: Mid Valley Pediatrics (MVP), Donna Medical Clinic (DMC), and Mercedes Children's Clinic/Mercedes Kids Med (MCC); **(4)** KMDMB's CLIA certificate was revoked by CMS effective May 10, 2011; and **(5)** the terms of 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8) mandate that CMS revoke the CLIA certificates of Mid Valley

Pediatrics (MVP), Donna Medical Clinic (DMC), and Mercedes Childrens Clinic/Mercedes Kids Med (MCC).

Accordingly, the CMS Motions for Summary Judgment filed August 16, 2011 must be, and they are, **GRANTED**. Petitioners' Motions for Summary Judgment filed September 9, 2011 are DENIED. On the authority of 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), CMS's determination to revoke the CLIA certificates of Mid Valley Pediatrics, Donna Medical Clinic, and Mercedes Childrens Clinic/Mercedes Kids Med is **AFFIRMED**.

/s/
Richard J. Smith
Administrative Law Judge