Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Hematology & Oncology Services, LLC,	)	Date: March 18, 2008
	)	
Petitioners,	)	Docket Nos. C-08-116, C-08-148, C-08-161, C-08-167, C-08-172
- v. -	)	Decision Nos. CR1754 CR1755 CR1756 CR1757 CR1758
Centers for Medicare & Medicaid Services.	)	

DECISIONS

In each of these cases I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) to revoke Petitioner's CLIA certificate.[1]

I. Background

Each Petitioner is a clinical laboratory doing business in the State of Louisiana. Each laboratory's operations are subject to the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law No. 100-578 (Section 353 of the Public Health Services Act, 42 U.S.C. § 263a), and its implementing regulations at 42 C.F.R. Part 493. CMS has been delegated authority by the Secretary of Health and Human Services (Secretary) to administer and enforce CLIA.

[1] There are five Petitioners, which I identify by location and Departmental Appeals Board docket number. These are: Slidell, C-08-116; Metairie, C-08-148; Marrero, C-08-161; Covington, C-08-167; and New Orleans, C-08-172. I am issuing consolidated decisions in these cases because the governing facts and law are identical in each of them. However, each Petitioner has an independent right to an appeal from these decisions.

On September 17, 2007, CMS notified each Petitioner separately by letter that it proposed to revoke that Petitioner's CLIA certificate. CMS based its determination to revoke in each case on the provisions of 42 C.F.R. § 493.1840(a)(8). The regulation directs CMS to revoke the CLIA certificate of any laboratory that is owned or operated by an individual or entity who owned or operated another laboratory whose CLIA certificate is revoked within the preceding two years. In each of these cases CMS determined that the laboratory was owned by the same individuals or entities who owned another laboratory – Hematology Oncology Specialists of Hammond, Louisiana (Hammond laboratory) – whose CLIA certificate was revoked less than two years previously.

Each Petitioner timely requested a hearing and each case was assigned to me for a hearing and a decision. I held a pre-hearing conference by telephone with the parties at which I advised them that it appeared that these cases all involved common and undisputed facts. The parties agreed that these cases could be heard and decided based on their written submissions.

CMS and all of the Petitioners filed motions asking that I decide these cases based on their written submissions. CMS offered eleven proposed exhibits in connection with its motion which I identify and receive as CMS Ex. 1 - CMS Ex. 11. Petitioners offered eight common proposed exhibits with their motions which I identify and receive as P. Ex. 1 - P. Ex. 8.[2] CMS then filed a reply brief.

II. Issues, findings of fact and conclusions of law

A. Issue

There is no dispute in these cases that each Petitioner is owned by the same individuals or entities who owned or operated the Hammond laboratory. In the absence of any dispute as to ownership, the sole issue in these cases is whether CMS was mandated to revoke each Petitioner's CLIA certificate based on a prior revocation of the Hammond laboratory's CLIA certificate.

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[2] CMS and Petitioners styled their motions as "motion for summary judgment, or in the alternative, motion for summary disposition." It is not necessary for me to reach conclusions in these cases concerning the appropriateness of summary judgment because there are no fact disputes. For purposes of these decisions, I assume to be true every fact that the parties allege.

B. Findings of fact and conclusions of law

I make findings of fact and conclusions of law (Findings) to support my decisions in these cases. I set forth each Finding below as a separate heading.

1. CMS is mandated to revoke each Petitioner's CLIA certificate because revocation of the Hammond laboratory's CLIA certificate is administratively final and may not now be challenged by Petitioners.

The gravamen of Petitioners' argument, which I discuss in more detail in Finding 2, is that CMS never, in fact, revoked the Hammond laboratory's CLIA certificate because the Hammond laboratory ceased all operations and surrendered its CLIA certificate prior to the date when CMS purported to revoke it. Therefore, according to Petitioners, the provisions of 42 C.F.R. § 493.1840(a)(8) simply are inapplicable to this case.

However, CMS's determination to revoke the Hammond laboratory's CLIA certificate is administratively final. The Hammond laboratory had the opportunity to contest the revocation determination when it was made. It could have argued then that CMS lacked the authority to revoke its CLIA certificate. Had it done so, it could have relied on the identical facts and arguments that Petitioners now make. But, the Hammond laboratory failed to challenge CMS's revocation determination.

Petitioners cannot now challenge that determination. Therefore, and as a matter of law, the CLIA certificate of the Hammond laboratory was revoked within the two years preceding the revocation determinations in these cases and CMS is authorized to revoke Petitioners' CLIA certificates.

The undisputed fact is that on September 5, 2006, CMS notified the Hammond laboratory in writing that it had determined that the Hammond laboratory failed to meet certain specified CLIA conditions. CMS advised the Hammond laboratory of its intent to impose remedies against it which might include revocation. CMS told the Hammond laboratory that, if it was dissatisfied with CMS's determination, it could request a hearing to contest it but that the hearing request had to be made within 60 days. CMS Ex. 1, at 4.

The Hammond laboratory did not file a hearing request to challenge the determination. Nor did the Hammond laboratory challenge CMS's subsequent determination, made on December 19, 2006, to revoke the Hammond laboratory's CLIA certificate. Indeed, at no time did the Hammond laboratory ever assert a challenge either to CMS's determination that it had failed to comply with CLIA requirements or its determination to revoke the Hammond laboratory's CLIA certificate.

Administrative hearings in cases involving CLIA are governed by regulations at 42 C.F.R. Part 498. 42 C.F.R. § 493.1844(a)(2). The regulations state that a party receiving a notice of an adverse determination must file its hearing request challenging that determination within 60 days of receiving it. 42 C.F.R. § 498.40(a)(2). If a determination is not challenged within the prescribed time it becomes administratively final.

CMS's determinations that the Hammond laboratory violated CLIA conditions and to revoke that laboratory's CLIA certificate are administratively final because the Hammond laboratory never challenged them. There is nothing in the regulations that gives me the authority to hear a challenge to an administratively final determination that is brought by a third party. Consequently, I have no authority to grant Petitioners a hearing to address the issue of whether CMS revoked the Hammond laboratory's CLIA certificate.

Petitioners now assert that they were unaware of any determination by CMS made against the Hammond laboratory. They contend that the employee at the Hammond laboratory who received the notices of remedy determinations from CMS never forwarded them to Petitioners or to their common management. I will assume this assertion to be true for purposes of these decisions. However, Petitioners are not benefitted by it. The regulations do not give a laboratory the right to request a hearing concerning an adverse determination made against another laboratory. The fact that an employee of the Hammond laboratory may have not communicated the contents of notices he or she received from CMS to his or her superiors does not give these Petitioners standing to challenge CMS's determinations concerning the Hammond laboratory.

But in fact, Petitioners' assertion would not give even the Hammond laboratory a basis for requesting a hearing now as to CMS's determinations concerning that laboratory. The regulation which governs the timing of a hearing request in a case involving CMS contains a good cause exception to the requirement that a hearing request be filed within 60 days from the date of a party's receipt from CMS of a notice of an adverse determination. 42 C.F.R. § 498.40(c)(2). Good cause has been interpreted universally to mean a situation beyond a party's ability to control which prevented that party from filing a timely request. The failure of an employee to communicate receipt of a notice to his or her superiors has never been held to constitute good cause because the employee clearly has it within his or her capacity to act appropriately in response to CMS's notice. Consequently, employee mis- or malfeasance is not good cause and no basis for extending the time within which a party may file its hearing request.

2. The undisputed facts do not support Petitioners' assertion that CMS was without authority to revoke the Hammond laboratory's CLIA certificate.

I would not sustain Petitioners' argument that there was no revocation of the Hammond laboratory's CLIA certificate even if CMS's determination to revoke that certificate was not administratively final. The undisputed facts do not support Petitioners' argument that CMS was without authority to revoke the Hammond laboratory's CLIA certificate.

Petitioners' argument begins with their contention that the Hammond laboratory ceased processing laboratory specimens on or before October 2, 2006, more than two months prior to the date when CMS determined to revoke the laboratory's CLIA certificate. They concede that the Hammond laboratory never informed CMS that it was withdrawing from CLIA or that it wished to voluntarily rescind its certificate. Rather, they contend that the cessation of business activity by the Hammond laboratory was a constructive withdrawal from CLIA. Petitioners reason that, once the Hammond laboratory effectuated its withdrawal, CMS could no longer impose any remedies against it under CLIA. Consequently, CMS's determination to revoke the Hammond laboratory's CLIA certificate is of no operative effect, according to Petitioners. And, therefore, according to them, they may not be subject to any adverse actions based on CMS's revocation of the Hammond laboratory's CLIA certificate.

For purposes of this decision I am assuming to be true Petitioners' assertion that the Hammond laboratory ceased all business operations by October 2, 2006, more than two months prior to the date that CMS sent it a notice that it had determined to revoke the laboratory's CLIA certificate. I find that, notwithstanding, CMS had the authority to revoke the Hammond laboratory's CLIA certificate in December 2006.

The Secretary has published policies which acknowledge that a laboratory may withdraw from CLIA by going out of business. State Operations Manual (SOM), sections 6256A, 6256B; CMS Ex. 11, at 1. But, the Secretary has also established as policy that CMS may nevertheless revoke a laboratory's CLIA certificate after a laboratory has gone out of business if it decides that the laboratory's owner or operator should be subject to the two-year prohibition against owning or operating another laboratory stated at 42 C.F.R. § 493.1840(a)(8). SOM section 6256C; CMS Ex. 11, at 1. Consequently, CMS is not denied authority to revoke a laboratory's CLIA certificate in the circumstance where the laboratory has previously gone out of business.

The reasons which underlie the Secretary's policy are obvious. CLIA makes the Secretary responsible for protecting the public from laboratory owners who are not complying with CLIA but who attempt to evade the reach of enforcement authority by pulling up stakes and moving their operations elsewhere. CLIA could be rendered ineffective if a laboratory owner was able to avoid its enforcement provisions simply by closing the laboratory's doors.

Petitioners argue that section 6256C of the SOM applies only in situations where a laboratory goes out of business while a revocation determination is pending. They contend that the Hammond laboratory went out of business before CMS determined to revoke its participation. Consequently, according to Petitioners, the Secretary's policy has no bearing on this case.

I find this argument to be without merit because it is based on an unrealistically narrow and inaccurate reading of the SOM and the notice that CMS sent to the Hammond laboratory on September 5, 2006. Petitioners rely on the fact that the notice does not literally tell the Hammond laboratory that its CLIA certificate was being revoked. Petitioners contend that the only remedy that CMS declared that it was imposing in the September 5 notice was a directed plan of correction. CMS Ex. 1, at 2.

However, and what Petitioners fail to address is that the September 5 notice explicitly warned the Hammond laboratory that other sanctions, including revocation, would be imposed against it if it failed to correct the noncompliance identified in the notice. CMS Ex. 1, at 3. And, the undisputed facts of these cases are that the Hammond laboratory never completed the corrective actions mandated by CMS. Indeed, as Petitioners acknowledge, it went out of business because it was unable to complete those actions.

Thus, adverse actions were pending against the Hammond laboratory at the time that it went out of business that would have inevitably led to that laboratory's CLIA certificate being revoked. That is precisely the process that is contemplated by section 6256C of the SOM.

Petitioners also argue that section 6256C of the SOM is inapplicable here because CMS failed to give the Hammond laboratory notice that CMS would revoke the laboratory's CLIA certificate despite the laboratory having gone out of business. But, the Hammond laboratory never notified CMS of its cessation of business activities. In effect, Petitioners argue that CMS may not revoke the Hammond laboratory's certification because it did not send a notice to respond to an event of which it was totally unaware. I find this argument to be without merit. There is nothing in CLIA, regulations, or the SOM that would require CMS to provide a laboratory with notice based on event about which CMS had no knowledge.

Finally, Petitioners contend that CMS *should have known* that the Hammond laboratory had gone out of business because it submitted no reimbursement claims for testing services provided in October and November 2006. I find that argument to be fanciful. CMS's regional office is not the entity to which the Hammond laboratory sent its reimbursement claims. It would have had no way of knowing whether a Medicare carrier or intermediary had stopped receiving claims. Moreover, the fact that a provider does not submit claims over a relatively short period of time does not mean, necessarily, that the provider has gone out of business.

3. Revocation of Petitioners' CLIA certifications is mandatory.

CMS has no discretion in applying 42 C.F.R. § 493.1840(a)(8). CLIA makes it plain that CMS must revoke the CLIA certification of any laboratory that is owned or operated by an individual or entity who owned or operated another laboratory whose CLIA certificate is revoked within the preceding two years. 42 U.S.C. § 263(a)(i)(3). In these cases revocation of the Hammond laboratory's CLIA certification mandates revocation of Petitioners' certifications as a consequence of their common ownership.

/s/
Steven T. Kessel
Administrative Law Judge