Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Walter Borg, MD,	)	
(CLIA No. 19D0979152),	)	Date: November 8, 2007
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-07-520
	)	Decision No. CR1688
Centers for Medicare & Medicaid	)	
Services.	)	
	)	

DECISION

I enter summary judgment in favor of the Centers for Medicare & Medicaid Services (CMS) sustaining CMS's determination to revoke Petitioner's (Walter Borg, M.D.) provider certificate under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

I. Applicable Law and Regulations

Under CLIA, the Secretary of the United States Department of Health and Human Services (Secretary) is authorized to inspect clinical laboratories and, in effect, license them to perform tests. CLIA prohibits a clinical laboratory from soliciting or accepting specimens for testing unless it has first received from the Secretary a certificate authorizing it to perform the specific category of tests which the laboratory intends to perform. 42 U.S.C. § 263a(b). CLIA directs the Secretary to establish standards to assure that clinical laboratories certified by the Secretary perform tests that are valid and reliable. 42 U.S.C. § 263a(f).

II. Background

Petitioner is a laboratory located in Lafayette, Louisiana, that holds a CLIA certificate of provider-performed microscopy (PPM) testing.

On October 18 and 24, 2006, the Louisiana Department of Health and Hospitals (LDHH) conducted a complaint investigation of Petitioner's laboratory and issued a statement of deficiencies form 2567 (SOD). ALJ Exhibits (Exs.) 1, 2.[1] CMS reviewed the survey report and determined that Petitioner was not in compliance with the conditions for participating in the CLIA program. The complete listing of Petitioner's deficiencies is found in the SOD. ALJ Ex. 2. Most significantly, Petitioner was found out of compliance with the condition for laboratory director, laboratories performing PPM procedures (42 C.F.R. § 493.1355), and the condition for inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories (all laboratories). 42 C.F.R. § 493.1771. ALJ Exs. 1, 2.

By letter dated April 20, 2007, CMS served notice of proposed sanctions on Petitioner pursuant to 42 C.F.R. §§ 493.1806(a), (b) and 1840(e). Specifically, CMS imposed the principal sanction of revocation of the laboratory's CLIA certificate pending a decision by an administrative law judge (ALJ), if Petitioner chose to appeal the sanction.

In accordance with 42 C.F.R. § 493.1842(b)(2), Petitioner was granted until April 30, 2007, to submit written evidence or other information against the imposition of sanctions. CMS found Petitioner's response to be insufficient to provide a basis to alter its decision to proceed with the enforcement action stated in the April 20, 2007 notice of proposed sanctions. ALJ Exs. 1, 3.

By letter dated June 13, 2007, Petitioner requested a hearing. This case was assigned to me for hearing and decision. On August 21, 2007, CMS filed a motion and memorandum of law in support of summary judgment (CMS Brief). As noted, no exhibits accompanied CMS's motion. Petitioner filed a response in opposition on September 18, 2007 (P. Brief), also with no supporting documentary evidence. CMS submitted a reply to Petitioner's opposition on September 26, 2007 (CMS Reply). Petitioner followed with a sur-reply received on October 9, 2007 (P. Reply).

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[1] The only documents submitted in this case came in with Petitioner's hearing request. Neither party asked that I admit these documents, but I enter them into evidence as ALJ Exs. 1-3, *motu proprio*. ALJ Ex. 1 is the April 20, 2007 notice of proposed sanctions; ALJ Ex. 2 is the SOD dated October 24, 2006; and ALJ Ex. 3 is a May 4, 2007 letter from CMS to Petitioner informing him that CMS was not altering its decision to proceed with the enforcement action noted in its April 20, 2007 notice letter.

For the reasons set forth below, I find that summary judgment is appropriate. Based on the documentary evidence, arguments of the parties, and applicable law and regulations, I find that there are no material issues of fact in dispute requiring an evidentiary hearing, and that CMS is entitled to judgment as a matter of law. I further find that Petitioner failed to meet the CLIA condition for laboratory director under 42 C.F.R. § 493.1355 and the condition for inspection requirements under 42 C.F.R. § 493.1771. Revocation of the laboratory's CLIA certificate is within CMS's discretion.

III. CMS's Contentions

CMS asserts that Petitioner's hearing request establishes that he is not contesting the factual findings in the SOD, but rather the choice of sanctions. Therefore, CMS maintains that the sole remaining issue is whether it abused its discretion by choosing to revoke Petitioner's CLIA certificate. CMS Brief at 7-9.

IV. Petitioner's Contentions

Petitioner concedes that he did not dispute the survey findings, but argues that the sanction is too severe. Petitioner raises several points, which I discuss below, as a basis for his contention that the revocation sanction is too severe. His principal argument, however, appears to be that CMS did not properly weigh the factors established in the regulations at 42 C.F.R. § 493.1804(d)[2] prior to selecting revocation as the sanction in this case. P. Brief at 4-7.

V. Issues

The issues in this case are whether:

> Petitioner failed to comply with one or more conditions of participation under CLIA, thereby giving CMS the authority to impose sanctions against Petitioner; and, if so,
>
> Whether CMS has abused its discretion by choosing revocation as the sanction for Petitioner's noncompliance.

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2 Petitioner refers to 42 C.F.R. § 493.1800(d), whereas the correct reference here is to 42 C.F.R. § 493.1804(d).

VI. Findings of Fact and Conclusions of Law

A. CMS may impose sanctions against Petitioner for his failure to comply with two condition-level deficiencies.

The regulations provide that a laboratory director must meet established qualifications and provide overall management and direction for a laboratory. 42 C.F.R. § 493.1355. The laboratory director's responsibility for the operation and management of the facility includes the prompt, accurate, and proficient reporting of test results. The laboratory director is also responsible for ensuring that testing is personally performed by an individual who meets all regulatory requirements. 42 C.F.R. § 493.1359.

Here, the laboratory director failed to fulfill the responsibilities of a laboratory director and restrict the laboratory's reporting of testing to the PPM procedures. The laboratory director also failed to ensure that testing personnel were qualified to perform testing. Through interviews, observations, and document review, the surveyors determined that the laboratory was conducting testing for specimens outside the scope of its CLIA microscopy certificate, that testing was being performed in the absence of appropriate supervision, and that testing was done by personnel lacking a license issued by the State of Louisiana. ALJ Ex. 2, at 4-26.

The condition-level inspection requirements were not met in that the laboratory failed to meet the requirements for maintaining a PPM procedure certificate by failing to restrict testing to its CLIA microscopy certificate. Based on surveyor observation and interviews, it was found that the laboratory failed to have all records and data accessible and retrievable within a reasonable period of time during the course of inspection to determine if the laboratory was in compliance. Additionally, there were no records that the laboratory had performed quality control for any test performed and reported, or that the laboratory was enrolled in proficiency testing. ALJ Ex. 2, at 26-51; 42 C.F.R. § 493.1771.

Petitioner concedes that he has not disputed the survey findings. P. Brief at 4. Consequently, I must conclude that CMS's determination that Petitioner incurred condition-level deficiencies is final and non-reviewable. It is, thus, my finding that, as a matter of law, Petitioner is in violation of 42 C.F.R. §§ 493.1355 and 1771. CMS is, therefore, justified in imposing sanctions for noncompliance with condition-level deficiencies.

B. CMS has not abused its discretion by choosing to revoke Petitioner's CLIA certificate.

Petitioner argues that the revocation sanction is too severe and that Petitioner is entitled to a hearing before an ALJ to resolve the appropriateness of the sanction imposed. The evidence that Petitioner would have me consider is that Petitioner believed that his laboratory was operating under a certificate of compliance and not a PPM certificate, and that there was a valid reason for the laboratory director's absence from the laboratory at the time of the survey. Petitioner also argues that CMS failed to appropriately weigh the factors set forth at 42 C.F.R. § 493.1804(d). P. Brief at 4-5. Petitioner's assertions have no basis in fact or law.

On October 18, 2006, laboratory personnel provided the surveyor with a copy of the CLIA certificate which indicated that the laboratory maintained a certificate of provider-performed microscopy procedures. ALJ Ex. 2, at 5. Thus, Petitioner had no reason to believe that the laboratory was operating under another category of CLIA certificate.

I agree with CMS that the absence of Petitioner and the laboratory director during the survey is irrelevant to CMS's discretion to impose a revocation sanction.

Concerning the penalty, Petitioner further argues that CMS has abused its discretion by imposing the most severe sanction, revocation, against him where the regulations require a weighing of factors under 42 C.F.R. § 493.1804(d), which lists a series of factors to be considered in making a determination regarding which sanction to impose against a laboratory. According to the regulation, CMS is granted discretion to consider *one or more* of the listed factors when opting for the imposition of sanctions against a deficient laboratory. CMS may also consider other factors not specifically mentioned in 42 C.F.R. § 493.1804(d).

As CMS notes (CMS Reply at 8), in a case such as this, where Petitioner concedes that: for several years he has been performing tests that he was not licensed to perform; he employed expired reagents in the testing process; he did not participate in a proficiency testing program; and he reported results for testing that he did not have the equipment to perform, a revocation sanction is most appropriate, and well within CMS's discretion. ALJ Ex. 2; *see Edison Medical Laboratories, Inc.,* DAB No. 1713, at 17-18.

The existence of either of the two condition-level deficiencies in this case is sufficient to support the principal sanction of revocation of Petitioner's CLIA certificate. The purpose of the Act is to ensure the accuracy and reliability of laboratory tests, and hence protect the

public health of all Americans. The condition-level deficiencies present in this case create a significant risk of inaccuracy and unreliability detrimental to the health of the American public.

VII. Conclusion

Petitioner failed to meet the condition-level requirements for laboratory director, laboratories performing PPM procedures (42 C.F.R. § 493.1355), and for inspection requirements applicable to all laboratories (42 C.F.R. § 493.1771). Accordingly, CMS has a basis to revoke Petitioner's CLIA certificate and to cancel Petitioner's approval to receive Medicare payments for its services. 42 C.F.R. § 493.1842(a)(1). Petitioner's owners or operators are prohibited from owning, operating or directing a laboratory for at least two years from the date of the revocation. 42 U.S.C. § 263a(i)(3); 42 C.F.R. § 493.1840(a)(8); 42 C.F.R. § 493.2.

/s/
José A. Anglada
Administrative Law Judge