Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Ward General Practice Clinic,	)	DATE: December 27, 1996
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-96-443
	)	Decision No. CR451
Health Care Financing Administration.	)	
	)	

DECISION

I sustain the determination of the Health Care Financing Administration (HCFA) to impose sanctions against Ward General Practice Clinic (Petitioner), pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Additionally, I direct that Petitioner's CLIA certification be revoked.

I. Background

On July 29, 1996, HCFA sent a notice to Petitioner advising it that HCFA had determined that Petitioner no longer met the requirements to perform testing under CLIA, because Petitioner manifested deficiencies that represented an immediate jeopardy to patients that it served. HCFA identified the conditions of participation under CLIA which it had determined Petitioner was not complying with. HCFA advised Petitioner that it had elected to impose sanctions against Petitioner, including: suspension of Petitioner's CLIA certificate, effective August 10, 1996; and cancellation of Petitioner's approval to receive Medicare payments for laboratory services, effective August 10, 1996. Additionally, HCFA advised Petitioner that it proposed revocation of Petitioner's CLIA certificate, based on a decision by an administrative law judge, should Petitioner appeal HCFA's determinations.

On August 8, 1996, HCFA again notified Petitioner that it was imposing sanctions against Petitioner. HCFA advised Petitioner that it had received from Petitioner a plan of correction which purportedly addressed deficiencies that had been identified by HCFA. HCFA advised Petitioner that the plan of correction did

not correct the deficiencies that HCFA had identified in its July 29, 1996 notice to Petitioner. HCFA affirmed that it would impose against Petitioner the sanctions that it had described in its July 29, 1996 notice.

Petitioner requested a hearing, and the case was assigned to me for a hearing and a decision. I held a prehearing conference, at which the parties agreed that the case could be heard and decided based on written submissions. HCFA submitted a brief. With its brief, HCFA submitted four exhibits (HCFA Ex. 1 - 4) and two affidavits (Affidavit of Molly Crawshaw and Affidavit of Veronica Margin). HCFA did not designate the two affidavits as exhibits, although it plainly intends them to be received into evidence. Therefore, I have designated the Affidavit of Molly Crawshaw as HCFA Ex. 5, and the Affidavit of Veronica Margin as HCFA Ex. 6.

Petitioner submitted a written statement, along with several attachments, which Petitioner designated as Enc # 1, Enc # 2A, Enc # 2B, Enc # 3, Enc # 4, and Enc # 5. It is apparent that Petitioner intends these attachments to its brief to be received into evidence as exhibits. Therefore, I am redesignating Petitioner's attachments as follows: Enc # 1 — P. Ex. 1; Enc # 2A — P Ex. 2; Enc # 2B — P. Ex. 3; Enc # 3 — P. Ex. 4; Enc # 4 — P. Ex. 5; Enc # 5 — P. Ex. 6.

Neither party has objected to my receiving into evidence the exhibits offered by the other party. Therefore, I receive into evidence HCFA Ex. 1 - 6 and P. Ex. 1 - 6. I base my decision in this case on the parties' exhibits and arguments and the governing law.

II. Issue, findings of fact and conclusions of law

The issue in this case is whether HCFA is authorized to impose sanctions against Petitioner, based on Petitioner's failure to comply with conditions of participation under CLIA. In sustaining HCFA's determination, I make the following findings of fact and conclusions of law (Findings), which I discuss in detail, below.

1. HCFA or its designee is authorized to conduct a validation inspection of any accredited or CLIA-exempt laboratory.

2. Where HCFA or its designee conducts an inspection of a laboratory and where, based on the inspection, HCFA determines the laboratory to be deficient in complying with CLIA requirements, HCFA may impose sanctions against the laboratory.

3. Where HCFA determines that a laboratory is not complying with a condition or conditions of participation under CLIA, HCFA may impose sanctions which may include: canceling the laboratory's approval to receive Medicare payments for its services; suspension of the laboratory's CLIA certificate; and revocation of the laboratory's CLIA certificate.

4. Where HCFA determines that a laboratory's failure to comply with a condition or conditions of participation under CLIA poses immediate jeopardy to the health and safety of patients, then HCFA may suspend the laboratory's CLIA certificate prior to a hearing before an administrative law judge concerning whether HCFA's determination is authorized.

5. Where an administrative law judge upholds a determination by HCFA to suspend a laboratory's CLIA certificate, based on finding that the laboratory's failure to comply with a condition or conditions of participation under CLIA poses immediate jeopardy to the health and safety of patients, then the suspension of the laboratory's CLIA certificate shall become a revocation of that certificate.

6. It is a matter of discretion whether a laboratory that has been found not to be complying with a CLIA condition or conditions of participation may be permitted, in lieu of imposition of sanctions against that laboratory, to change the nature of its operations so as to provide only lower levels of testing.

7. Petitioner failed to comply with CLIA conditions of participation stated at 42 C.F.R. §§ 493.801, 493.1201, 493.1227, 493.1245, 493.1247, 493.1251, 493.1403, 493.1441, and 493.1701.

8. Petitioner's failure to comply with CLIA conditions of participation posed immediate jeopardy to the health and safety of patients.

9. Petitioner did not correct its failure to comply with CLIA conditions of participation.

10. Petitioner has a history of not complying with CLIA requirements.

11. HCFA was authorized to impose sanctions against Petitioner, including: canceling the Petitioner's approval to receive Medicare payments for its services; suspension of Petitioner's CLIA certificate; and revocation of Petitioner's CLIA certificate.

12. It is reasonable to deny approval to Petitioner to convert its operations to a lower level of testing, in lieu of imposing sanctions against Petitioner, in light of the nature of Petitioner's failure to comply with CLIA requirements, its history of noncompliance, and its failure to correct its noncompliance.

III. Discussion

A. Governing law (Findings 1 - 6)

The Secretary of the United States Department of Health and Human Services (Secretary) has published regulations which implement CLIA. 42 C.F.R. Part 493. In these regulations, the Secretary has established both performance criteria for clinical laboratories and procedures for assuring that clinical laboratories comply with statutory requirements.

The regulations authorize HCFA or its designee to conduct validation inspections of any accredited or CLIA-exempt laboratory, in order to determine whether the laboratory is in compliance with CLIA requirements. 42 C.F.R. § 493.1780(a). The regulations confer broad enforcement authority on HCFA, in order to assure that laboratories comply with CLIA. 42 C.F.R. § 493.1800. Where HCFA determines that a laboratory is not complying with one or more CLIA conditions, HCFA may impose principal sanctions against that laboratory which include suspension and/or revocation of the laboratory's CLIA certificate. 42 C.F.R. § 493.1806(a), (b). Additionally, HCFA may cancel a laboratory's approval to receive Medicare payments for its services, where the laboratory is found not to be complying with one or more CLIA conditions. 42 C.F.R. § 493.1807.

A laboratory that is dissatisfied with a determination by HCFA to impose sanctions against it may request a hearing before an administrative law judge to contest HCFA's determination. 42 C.F.R. § 493.1844. In most circumstances, a determination to suspend, limit, or revoke a CLIA certificate will not become effective until after decision by an administrative law judge upholding HCFA's determination to impose such a remedy. 42 C.F.R. § 493.1844(d)(2)(i). However, if HCFA determines that a laboratory's failure to comply with CLIA requirements poses immediate jeopardy to patients, then HCFA's determination to suspend or limit a laboratory's CLIA certificate will become effective in advance of a hearing and decision by an administrative law judge, after HCFA gives notice to the laboratory of its determination. 42 C.F.R. § 493.1844(d)(2)(ii). Where an administrative law judge decides to uphold a determination by HCFA to suspend a laboratory's CLIA certificate, based on a finding that the failure by the laboratory to comply

with CLIA requirements poses immediate jeopardy to the health and safety of patients, then the suspension automatically becomes a revocation of the laboratory's CLIA certificate. 42 C.F.R. § 493.1844(d)(4).

The regulations are silent as to whether a laboratory that has been found not to be complying with CLIA requirements may convert its operations to a lower level of testing in order to avoid the imposition of sanctions against it. I conclude that HCFA has discretion to determine whether, as an alternative to imposing sanctions against a laboratory, it should permit that laboratory to convert its operations to a lower level of testing. It is reasonable for HCFA to consider the nature of the laboratory's noncompliance with CLIA requirements, its compliance history, and the efforts that the laboratory may have made to comply with CLIA requirements, in determining whether to exercise discretion to permit a noncompliant laboratory to convert its operations to a lower level of testing in lieu of imposing sanctions against that laboratory.

B. Relevant facts (Findings 7 - 10)

Petitioner is a clinical laboratory located in New Orleans, Louisiana. HCFA Ex. 2 at 1. On July 18, 1996, the Louisiana Department of Health and Hospitals (Louisiana State agency), acting as HCFA's designee, conducted a CLIA compliance survey of Petitioner. The Louisiana State agency found that Petitioner was not complying with nine CLIA conditions. Id. These conditions are stated at 42 C.F.R. §§ 493.801, 493.1201, 493.1227, 493.1245, 493.1247, 493.1251, 493.1403, 493.1441, and 493.1701. Id. The Louisiana State agency found Petitioner's failure to comply with these CLIA conditions to be so egregious as to pose immediate jeopardy to the patients served by Petitioner. Id.

On July 29, 1996, HCFA advised Petitioner that it agreed with the findings made by the Louisiana State agency. HCFA Ex. 2 at 1. HCFA told Petitioner that it was prepared to impose sanctions against Petitioner consisting of suspending Petitioner's CLIA certificate and canceling Petitioner's approval to receive Medicare payments for laboratory services, effective August 10, 1996. Additionally, HCFA advised Petitioner that it would seek revocation of Petitioner's CLIA certificate, should Petitioner ask for review by an administrative law judge of HCFA's determinations. Id.

HCFA advised Petitioner that a laboratory that does not meet a CLIA condition may not be certified to participate under CLIA. HCFA Ex. 2 at 3. HCFA instructed Petitioner to submit a plan of correction. Id. It advised Petitioner that, if Petitioner alleged credibly that it was complying with CLIA requirements, HCFA would determine whether Petitioner was, in fact, complying with those requirements. Id. HCFA advised Petitioner that, if

Petitioner alleged that it was complying with CLIA requirements, a resurvey would be conducted of Petitioner to determine whether, in fact, it was complying with those requirements. HCFA told Petitioner that, if Petitioner demonstrated at a resurvey that it had attained compliance with CLIA requirements, then sanctions would not be imposed against Petitioner. Id.

On July 29, 1996, Petitioner submitted a purported plan of correction. HCFA Ex. 3. The document does not explain how Petitioner intended to correct the deficiencies that were identified in its operations. Rather, Petitioner tacitly admitted that it had not been complying with CLIA requirements, and averred that, as of July 24, 1996, only waived procedures and physician performed testing was being done by Petitioner. Id.

Petitioner's plan of correction does not explain what Petitioner means by the terms "waived procedures" and "physician performed testing." See HCFA Ex. 3. However, regulations define the terms "waived tests" and "provider-performed microscopy (PPM) procedures." 42 C.F.R. §§ 493.15, 493.19. I conclude that Petitioner was referring to waived tests and PPM procedures when it asserted that, as of July 24, 1996, it was performing only waived tests and physician performed testing.

Under the regulations, waived tests are simple laboratory examinations and procedures which are cleared by the Food and Drug Administration for home use, employ methodologies that are so simple and accurate as to render the likelihood of erroneous results to be negligible, and which pose no reasonable risk of harm to the patient if performed incorrectly. 42 C.F.R. § 493.15. The regulations characterize PPM procedures as being tests of moderate complexity. 42 C.F.R. §§ 493.5(a)(2), 493.19(b)(2). In order to be a PPM procedure, a test must be performed personally, by a physician, a midlevel practitioner, or a dentist, on a specimen obtained during a visit by the patient. 42 C.F.R. § 493.19(b)(1)(i) - (iii).

A PPM procedure must be performed primarily by microscope. 42 C.F.R. § 493.19(b)(3). A specimen for a PPM procedure is labile, or delay in performing the procedure might compromise the accuracy of the test result. 42 C.F.R. § 493.19(b)(4). In a PPM procedure, control materials are not available to monitor the entire testing process. 42 C.F.R. § 493.19(b)(5). Limited specimen handling or processing is required in performing a PPM procedure. 42 C.F.R. § 493.19(b)(6). A laboratory may perform PPM procedures only if it limits its testing to waived tests and to the tests that are specified in 42 C.F.R. § 493.19(c). The specified tests include urine sediment examinations. 42 C.F.R. § 493.19(c)(6). It is evident from the definition of a PPM procedure that such a procedure is more than a simple test with no risk to a patient if done improperly. Plainly, there exists a

potential for harm to a patient if a PPM procedure is not performed properly.

On August 8, 1996, HCFA advised Petitioner that it had concluded that Petitioner's plan of correction did not correct the deficiencies that had been identified by the Louisiana State agency and with which HCFA had concurred. HCFA Ex. 4 at 1. HCFA advised Petitioner that no provisions existed under CLIA regulations to permit a laboratory to performed only waived tests and PPM procedures to avoid the imposition of sanctions against the laboratory for failure to comply with CLIA requirements. Id. HCFA advised Petitioner that it was imposing the sanctions enumerated in HCFA's July 29, 1996 letter to Petitioner. Id. at 1 - 2; see HCFA Ex. 2.

I conclude that HCFA has established that, as of July 18, 1996, Petitioner manifested failures to comply with CLIA conditions and that these deficiencies posed immediate jeopardy to patients. HCFA introduced evidence that Petitioner was not complying with CLIA conditions as of July 18, 1996. The evidence includes the survey report generated by the Louisiana State agency at its July 18, 1996 survey of Petitioner. HCFA Ex. 1. The evidence is reinforced and corroborated by the affidavit of Veronica Margin, one of the surveyors who conducted the July 18, 1996 survey. HCFA Ex. 6. In her affidavit, Ms. Margin provides convincing and unrebutted evidence that Petitioner's deficiencies posed immediate jeopardy to patients. Id.

Petitioner has not denied that the deficiencies identified by HCFA in fact existed as of July 18, 1996. Nor has Petitioner denied that the deficiencies posed immediate jeopardy to patients. Indeed, as I discuss above, the plan of correction which Petitioner submitted is a tacit admission by Petitioner of the deficiencies that were identified in Petitioner's operations. HCFA Ex. 3.

I conclude also that Petitioner did not correct these deficiencies at any time after July 18, 1996. Petitioner's plan of correction does not explain how Petitioner intended to remedy the deficiencies identified by the Louisiana State agency and HCFA, except to say that Petitioner had converted its operations to waived tests and PPM procedures. See HCFA Ex. 3. That assertion does not address the specific deficiencies identified by HCFA.

Petitioner asserts that it did correct the deficiencies identified by the Louisiana State agency and by HCFA. Petitioner's Statement, dated November 15, 1996, at 1. Petitioner seems to be asserting that it corrected the deficiencies by ceasing to perform those tests and procedures in the performance of which Petitioner was found to be deficient. I do not find that Petitioner corrected its deficiencies simply by

ceasing to perform certain tests and procedures. The deficiencies that the Louisiana State agency identified not only involved specific failures by Petitioner to comply with protocols and safety procedures in performing certain identified tests, they involved pervasive and systematic failures by Petitioner to comply with quality control procedures that apply to clinical laboratories. HCFA Ex. 1; HCFA Ex. 6. Petitioner offers no assurance that it has corrected these pervasive and systematic failures merely by ceasing to perform certain tests.

The evidence establishes that Petitioner was found to be deficient previously, approximately two years prior to the July 18, 1996 survey of Petitioner. HCFA Ex. 5. Thus, Petitioner has a history of failing to comply with CLIA requirements.

C. Application of the law to the evidence (Findings 11 - 12)

As I find at Part III.B. of this decision, Petitioner has not complied with CLIA conditions since at least July 18, 1996. Petitioner's noncompliance poses immediate jeopardy to the health and safety of patients. Petitioner has not corrected its deficiencies. As a consequence, HCFA is authorized to impose sanctions against Petitioner. These include suspension of Petitioner's CLIA certificate and canceling Petitioner's authority to receive Medicare reimbursement for its services. 42 C.F.R. § 493.1807. Furthermore, my conclusion that HCFA is authorized to suspend Petitioner's CLIA certificate means that Petitioner's certificate is revoked, based on the evidence which establishes that Petitioner's noncompliance poses immediate jeopardy to the health and safety of patients. 42 C.F.R. § 493.1844(d)(4).

As I find above at Part III.A. it is a matter of HCFA's discretion whether to permit a laboratory to convert its operations to procedures and tests other than those in the performance of which it has been found to be deficient, in lieu of imposing sanctions against that laboratory. Here, HCFA has elected not to permit Petitioner to convert its operations to waived tests and PPM procedures. I find that exercise of discretion to be reasonable.

Petitioner's noncompliance with CLIA requirements is a systematic failure by Petitioner to comply with basic protocol governing the performance of tests. Petitioner's noncompliance is so egregious as to constitute immediate jeopardy to the health and safety of patients. Given that, coupled with Petitioner's failure to correct or even to address its noncompliance, HCFA has ample justification to conclude that conversion of Petitioner's operations would not be a viable substitute for the imposition of sanctions.

Moreover, the deficiencies identified in Petitioner's operations raise serious questions as to whether Petitioner would be capable of converting its operations to waived tests and, in particular, PPM procedures, without continuing to pose health and safety threats to patients. Petitioner was found to be deficient in performing tests of moderate complexity. HCFA Ex. 1. PPM procedures are tests of moderate complexity. 42 C.F.R. § 493.5(a)(2), 493.19(b)(2). Petitioner was found to be deficient in performing urinalysis. Id. Certain types of urinalysis are among the tests which are listed as PPM procedures. 42 C.F.R. § 493.19(c). Finally, Petitioner's history of noncompliance gives HCFA additional justification for not permitting Petitioner to convert its operations to waived tests and PPM procedures.

IV. Conclusion

I conclude that HCFA is authorized to impose sanctions against Petitioner, including suspending Petitioner's CLIA certificate and canceling Petitioner's authority to receive reimbursement from Medicare. I direct that Petitioner's CLIA certification be revoked, inasmuch as Petitioner's failure to comply with CLIA requirements poses immediate jeopardy to patients and Petitioner has not corrected outstanding deficiencies.

/s/

Stephen J. Ahlgren

Administrative Law Judge