Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
California Medical Associates Laboratory,	DATE: May 30, 1997
Petitioner,	
- v. -	Docket No. C-96-261 Decision No. CR476
Health Care Financing Administration.	

DECISION

I sustain the determination of the Health Care Financing Administration (HCFA) to impose the principal sanctions of suspension of Petitioner's certificate to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578 (42 U.S.C. § 263a) and cancellation of all Medicare payments under Title XVIII of the Social Security Act for services furnished by the laboratory.

On March 24, 1995, the California Department of Health Services, Laboratory Field Services (the State agency) conducted a CLIA survey of Petitioner and identified 10 condition-level deficiencies. As a result of that survey, and pursuant to the recommendation of the State agency, HCFA notified Petitioner by letter dated June 20, 1995 that it was suspending the laboratory's CLIA certificate effective June 26, 1995 and cancelling all Medicare payments to the laboratory as of that date. HCFA's letter noted that the deficiencies found by the State posed a threat to and immediately jeopardized patient health and safety. Petitioner was advised that it could avoid the proposed sanctions by submitting a credible allegation of compliance and evidence documenting that the immediate jeopardy had been removed and that the laboratory had taken action to correct all of the condition-level deficiencies.

HCFA received a plan of correction from Petitioner dated July 24, 1995. The State agency conducted a revisit of the laboratory on December 1, 1995 to verify compliance. The surveyors found that immediate patient jeopardy had been removed, but found that the laboratory remained out of compliance with three CLIA conditions,

and in addition, many of the standard level deficiencies cited at the March 24, 1995 survey were also found to be uncorrected. By letter dated January 12, 1996, HCFA advised Petitioner that it would initiate action to impose revocation of Petitioner's CLIA certificate and cancellation of approval to receive Medicare payments for all laboratory services if credible documentation that all deficiencies had been corrected was not submitted to the State agency within 10 days. In addition, the letter noted that Petitioner had failed to pay outstanding fees of $2991 to the CLIA program, and that this failure, if not corrected within 10 days, could constitute an independent basis for suspension, revocation, or limitation of the laboratory's certificate.

By letter dated February 1, 1996, HCFA again wrote Petitioner advising that the principal sanctions of suspension of the laboratory's CLIA certificate and cancellation of approval to receive Medicare payments were being imposed effective February 21, 1996, and further, that Petitioner's CLIA certificate would be revoked effective April 6, 1996 unless a timely hearing request was received prior to that date.

Petitioner paid the outstanding CLIA fees and submitted a second credible allegation that it was in compliance. On March 4, 1996, the State agency conducted a second on-site revisit to verify compliance. During the revisit, the laboratory was found still out of compliance with the three condition-level deficiencies noted during the two prior surveys as well as out of compliance with several of the standards cited during both the March 24 and December 1, 1995 surveys.

By letter dated March 12, 1996, HCFA formally advised Petitioner that because of its continued failure to correct outstanding deficiencies, HCFA was imposing the principal sanctions of suspension of the laboratory's CLIA certificate and cancellation of all Medicare payments for laboratory services, which was to become effective on May 16, 1996, if a hearing was not requested prior to that date. Medicare payments would be cancelled effective April 1, 1996, regardless of whether Petitioner requested a hearing. Petitioner was also advised that if the determination to suspend the laboratory's CLIA certificate was upheld on appeal, information regarding the suspension would appear in the Laboratory Registry of CLIA sanctions for the calendar year of the suspension, and the general public would be notified through a notice published in a local newspaper.

On May 14, 1996, Petitioner submitted another allegation of compliance. HCFA reviewed the allegation of compliance, found it to be lacking in specificity and documentation, and by letter dated June 3, 1996, notified Petitioner that it was upholding its

prior determinations.[1] Petitioner filed its request for hearing on April 16, 1996, appealing HCFA's final determination issued on March 12, 1996.

This case was originally assigned to Administrative Law Judge Jill Clifton who held telephone prehearing conferences on June 20 and July 2, 1996. By Order dated July 3, 1996, Judge Clifton summarized the prehearing discussion as follows:

> Petitioner admits that it had condition-level deficiencies during the State agency survey in March 1995. Petitioner admits further that, despite making many corrections and improvements, it still had condition-level deficiencies which had not been corrected at the time of State agency revisits in December 1995 and March 1996. Petitioner contends, however, that because it acknowledged the deficiencies, and had ceased much of its laboratory testing and was willing voluntarily to cease the remainder of its laboratory testing, it is unfair to sanction Petitioner with suspension.

Since it appeared that there were no facts in dispute, Judge Clifton directed the parties to brief the issue of whether Petitioner's voluntary cessation of laboratory testing, and willingness to cease all laboratory testing, prevents HCFA from going forward with the suspension of Petitioner's CLIA certificate. The parties have subsequently exchanged those briefs and documentary evidence in support thereof. There has been no objection to the proposed documentary evidence raised by either party.

This case was reassigned to me on April 24, 1997 for hearing, related proceedings, and decision. I find too that there are no facts in dispute in this matter. Furthermore, the issue of law stated above as framed by Judge Clifton with the agreement of the parties is such that oral argument is unnecessary. I have determined also that an in-person hearing is not necessary. I will decide this case on the basis of the record before me, the stipulations of the parties as to the facts, the parties' arguments, and the applicable law.

There being no objection by the parties, I hereby admit into evidence Petitioner's exhibits (P. Ex.) 1 through 13 and HCFA exhibits (HCFA Ex.) 1 through 8.

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[1] Because Petitioner submitted payment of outstanding CLIA fees, 42 C.F.R. § 493.1840(a)(3) was removed by HCFA as a basis for suspension of its CLIA certificate. Because of this revision to HCFA's proposed sanctions, Petitioner was given a new notification of its hearing rights within 60 days of the March 12th letter. HCFA Brief at 7.

I. Issue, findings of fact, and conclusions of law

The issue in this case is whether Petitioner's voluntary cessation of laboratory testing, and willingness to cease all laboratory testing, prevents HCFA from going forward with the suspension of Petitioner's CLIA certificate.

In sustaining HCFA's position that it may proceed with sanctions against Petitioner despite Petitioner's admission of the existence of condition-level deficiencies and voluntary cessation of laboratory testing, 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: cancelling 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. On and before March 24, 1995, and continuing thereafter at all times relevant hereto, Dr. Anthony S. Awad was the owner/operator of Petitioner, California Medical Associates Laboratory, and was certified to perform testing under CLIA. HCFA Exs. 2, 3.

5. The statute at 42 U.S.C. § 263a(i)(1) and its implementing regulations at 42 C.F.R. Part 493 set forth participation requirements and penalties for noncompliance with those requirements.

6. Petitioner admits that the laboratory was not in compliance with 10 condition-level requirements as of the date of the initial survey, March 24, 1995, to-wit:

(1) Patient test management; moderate or high complexity testing, or both (42 C.F.R. § 493.1101);

(2) Microbiology (42 C.F.R. § 493.1225);

(3) Syphilis serology (42 C.F.R. § 493.1239);

(4) General immunology (42 C.F.R. § 493.1241);

(5) Routine chemistry (42 C.F.R. § 493.1245);

(6) Endocrinology (42 C.F.R. § 493.1247);

(7) Hematology (42 C.F.R. § 493.1253);

(8) Laboratories performing moderate complexity testing; laboratory director (42 C.F.R. § 493.1403);

(9) Laboratories performing high complexity testing; Laboratory Director (42 C.F.R. § 493.1441); and

(10) Quality assurance; moderate or high complexity, or both (42 C.F.R. § 493.1701).

7. Petitioner remained out of compliance with condition-level requirements as determined by survey revisits on December 1, 1995 and again on March 4, 1996 and as stated at 42 C.F.R. § 493.1101; 42 C.F.R. § 493.1403; and 42 C.F.R. § 1701.

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

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

10. Because of the continued failure of Petitioner to correct outstanding deficiencies cited since the March 24, 1995 survey, HCFA was authorized to impose the principal sanctions of suspension of Petitioner's CLIA certificate and cancellation of Petitioner's approval to receive Medicare payments for its laboratory services.

11. HCFA's choice of sanctions was neither arbitrary, capricious, nor an abuse of its discretion.

12. As a matter of law, HCFA's authority to impose principal sanctions is in no way constrained or affected by Petitioner's admission of wrongdoing, its efforts to come into compliance, or its cessation of all testing.

II. Discussion

A. Governing law

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 a 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).

B. Relevant Findings

Finding 10

The facts in Findings 1 through 9 are uncontroverted, and accordingly, will not be addressed herein.

Petitioner does not appear to challenge the Secretary's authority to impose principal sanctions but argues rather that the Secretary should not exercise that authority in this case. Petitioner's argument is essentially that imposition of sanctions against it is unfair, arbitrary, and capricious.

Petitioner notes that it made a good faith effort to correct deficiencies by: (1) correcting conditions such that immediate jeopardy was removed; (2) offering voluntarily "a shut down of the whole operation and testing"; (3) purchasing new laboratory

equipment; and (4) taking steps to acquire new space. Petitioner's Brief at 7.

Petitioner notes further that the sanctions imposed constitute "a very harsh punishment" that may affect Dr. Awad's entire medical practice in light of the fact that publication of the sanctions will occur in local media. Petitioner's Brief at 8, 9.

Moreover, Dr. Awad contends that he was not the medical director for at least a portion of the time in question (although he admits he was the owner/operator of the laboratory at all times) and that most of the laboratory's problems were due to inadequacies on the part of his employees. Petitioner's Brief at 8, 10.

I find little merit in, or sympathy for, the arguments advanced by Petitioner. First, it is well established by the evidence of record and by Dr. Awad's own admission that Petitioner was out of compliance with major conditions of participation. Further, the record shows that Petitioner remained out of compliance for a period well in excess of one year as found on three on-site survey visits or revisits. Given these circumstances, the law is clear that the Secretary may impose principal sanctions against Petitioner. HCFA may impose one or more sanctions specified in 42 C.F.R. § 493.1806(a) when a laboratory is found out of compliance with one or more CLIA conditions. Subsection (b) of that regulation further provides that HCFA may impose any of three principal CLIA sanctions, which are: suspension, limitation, or revocation of any type of CLIA certificate. Likewise, the Act at 42 U.S.C. § 263a(i)(1) provides for the principal sanction of suspension, revocation, and limitation of a laboratory's CLIA certificate when that laboratory is found not to be in compliance with the provisions of the statute and its implementing regulations. HCFA has the authority to impose the principal sanction of suspension given the facts of this case. Further, 42 C.F.R. § 493.1808 provides that when HCFA takes action to suspend or revoke a CLIA certificate it concurrently cancels the laboratory's approval to receive Medicare payment for its services.

Finding 11

Having established that HCFA has the authority to impose the sanctions proposed in this case, I next examine whether that action was "unfair" as alleged by Petitioner, or put another way, whether HCFA's choice of sanctions was arbitrary, capricious, or an abuse of discretion.

Under the regulations, while HCFA has the authority to impose principal sanctions, it also has the authority to impose one or more alternative sanctions in lieu of, or in addition to, the principal sanctions. 42 C.F.R. § 493.1806(c). HCFA has discretion in which sanction or sanctions to impose. That is not

to say, however, that HCFA is free to select whichever sanction it desires. On the contrary, 42 C.F.R. § 493.1804(d) provides guidance to HCFA as to some of the factors which must be considered in choosing a sanction.

In this case, at least one of the primary reasons that HCFA sanctioned Petitioner was because of Petitioner's failure to correct deficiencies over a prolonged period of time. In its notice to Petitioner dated March 12, 1996, HCFA advised Petitioner that it was imposing principal sanctions due to Petitioner's continued failure to correct outstanding deficiencies cited during the March 24, 1995 survey. HCFA Ex. 6.

I recognize that HCFA has been granted a considerable amount of discretion in selecting which sanctions it will impose. So long as that discretion is exercised in a manner consistent with the general purposes of the legislation, i.e. --

> (1) to protect all individuals served by laboratories against substandard testing of specimens;
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> (2) to safeguard the general public against health and safety hazards that might result from laboratory activities; and
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> (3) to motivate laboratories to comply with CLIA requirements so that they can provide accurate and reliable test results; 42 C.F.R. § 493.1804(a).

and, so long as those sanctions are based on factors set forth in the Act and its implementing regulations, HCFA's determination as to which sanctions to impose cannot be said to be arbitrary, capricious, or an abuse of its discretion. Under these circumstances, HCFA's exercise of discretion will be found to be reasonable, and its decision will not be disturbed. Given Petitioner's repeated and admitted noncompliance in this case, I find that HCFA acted within its statutory authority in imposing the sanctions in this case.

Finding 12

Finally, with respect to Petitioner's argument that HCFA should have considered the laboratory's efforts to comply, Petitioner's admission of wrongdoing, and Petitioner's voluntary offer to "shut down," I conclude that HCFA did consider Petitioner's efforts to comply, and found those efforts wanting.

The fact that Petitioner admitted noncompliance, yet failed to comply and continues to fail to comply was considered by HCFA in its imposition of sanctions. This clearly is not a mitigating circumstance under the regulations.

Further, nothing in the Act nor the regulations prohibits HCFA from imposing sanctions even if a laboratory ceases operations voluntarily. Indeed, if laboratories were allowed to circumvent the imposition of sanctions by closing down for a period of time, and then reopening when they saw fit, without correcting the deficiencies cited by the State agency, the government's enforcement powers could be seriously eroded. This clearly would be contrary to the intent of the applicable statutory and regulatory provisions.[2]

It is important to note here, however, that again HCFA is exercising its statutory discretion in a manner it deems consistent with its duty to protect the public health and safety, and it is treating this Petitioner in the same manner it would treat others similarly situated, in accordance with the Act, the regulations, and its own policy. Accordingly, I find that HCFA's determination to impose sanctions against Petitioner is in no way constrained or limited by Petitioner's admission of wrongdoing or his offer to voluntarily cease laboratory testing.

III. 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.

/s/

Stephen J. Ahlgren

Administrative Law Judge

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[2] Counsel for HCFA notes that it is HCFA's longstanding policy, as set forth in HCFA's Regional Office Manual, section 5406, Rev. 61, to proceed with sanctions against a laboratory which discontinues testing where it is determined that the action is necessary to protect the public, for example by appropriate notification through media and the Laboratory Registry, which is the case with respect to Petitioner. HCFA Brief at 13, 14. As can be seen from Petitioner's brief, it is precisely that public notification to which it most objects.